

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

AUG 1 3 2018

# UNITED PARCEL SERVICE

Mr. Christopher Sebley Zoetis 1040 Swabia Court Durham, North Carolina 27703

> Re: Case No: FIFRA-04-2018-3257 Stop Sale, Use, or Removal Order

Dear Mr. Sebley:

Enclosed is a Stop Sale, Use or Removal Order (SSURO) that the U.S. Environmental Protection Agency is issuing to Zoetis pursuant to the authority set forth in Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C.§ 136k. This SSURO shall become effective immediately.

This SSURO is being issued for: (1) 1,152 cases of the misbranded imported pesticide product Inovotabs (EPA Reg. No. 71847-3-1007) that wereshipped as identified in the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) Data Processing System received by the EPA Region 4 on May 1, 2018, under Entry Number U16-10064192; (2) 1,200 cases of the misbranded imported pesticide product Inovotabs (EPA Reg. No. 71847-3-1007) that were shipped as identified in the CBP ACE Data Processing System received by the EPA Region 4 on July 29, 2018, under Entry Number U16-10084042.

The SSURO prohibits all further sale and distribution of the imported pesticide product Inovotabs until the EPA vacates the SSURO in writing. The cases of Inovotabs should be moved to Contrapac, Inc. located at 675 Great Southwest Parkway, Atlanta, Georgia 30336 as instructed in the SSURO for relabeling. Please take notice that any violation of the terms or provisions of the SSURO may result in imposition of civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 1361. Also, a civil penalty of up to \$19,446 for each violation that is the subject of this SSURO may be assessed for violations of FIFRA. Prior to the assessment of any penalty, however, Zoetis will be given the opportunity to request a hearing and/or provide information that may mitigate any penalty amount.

Please contact Kimberly Tomczak of the EPA Region 4 staff, the Case Development Officer (CDO) for this case, at (404) 562-8987 or via email at tomczak kimberly@epa.gov within 10 days of receipt of this SSURO. At that time, Zoetis should indicate what actions will be taken to ensure that the product is not released for sale or distribution.

The EPA developed an information sheet entitled "U.S. EPA Small Business Resources" to help small businesses understand federal and state environmental laws and rights under the Small Business Regulatory Enforcement Fairness Act. The information sheet can be found on the internet at: https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf.

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 4

IN THE MATTER OF:	)	STOP SALE, USE, OR
Zoetis	)	REMOVAL ORDER
<b>D</b>	)	FIFRA-04-2018-3257
Respondent.	)	

### I. AUTHORITIES AND BACKGROUND

- 1. Section 13(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), authorizes the Administrator of the U.S. Environmental Protection Agency to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that such pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA. The Administrator of the EPA has delegated this authority under FIFRA to the Regional Administrators by the EPA Delegation 5-12. The Regional Administrator, Region 4, has redelegated this authority to the Director of the Air, Pesticides and Toxics Management Division by the EPA, Region 4, Delegation 5-12. Pursuant to these delegations, the Director of the Air, Pesticides and Toxics Management Division has the authority to issue a Stop Sale, Use or Removal Order (SSURO) in this matter.
- 2. This SSURO is being issued to Zoetis, a privately held company with its principal place of business located at 10 Sylvan Way, Number 105, Parsippany, New Jersey 07054 (hereinafter Zoetis or Respondent).

- On or around April 30, 2018, the licensed customs broker American Cargo Express, Inc. (American) submitted entry documents via the U. S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) Data Processing System on behalf of Medentech for the importation of one shipment of the pesticide product Inovotabs (EPA Reg. No. 71847-3-1007) which contained a total of one thousand two hundred (1,200) cases, each case weighing 23.2 pounds. The Importer of Record in this matter is Medentech, a business located at Whitemill Industrial Estate, Wexford, Ireland.
- 4. The information provided to the EPA Region 4 through the CBP ACE System indicated that the shipment of Inovotabs was scheduled to arrive at the Port of Charleston, South Carolina on April 27, 2018.
- 5. After reviewing the ACE entry, the EPA asked Medentech and American on May 1, 2018, to upload into the ACE system a legible copy of the label that was affixed to the 1,200 cases of the Inovotab pesticide product. American uploaded the label, and on May 11, 2018, the EPA reviewed the ACE entry a final time and determined that the label uploaded by American, which American had represented to be the label on the product cases, included incorrect information that was not compliant with the EPA master label for the product.
- 6. Pursuant to 40 C.F.R. §§ 156.10(a)(5) and 156.10(f) (Labeling Requirements), every pesticide product must bear a label containing the information required by FIFRA and the regulations including, but not limited to, the product's EPA registration number, the producing establishment's EPA establishment number, directions for use, precautionary language and the storage and disposal information.

- 7. On April 11, 2018, the EPA Region 4 informed American by email that the label submitted for the Inovotabs pesticide product being imported by Medentech did not correspond with the pesticide's most current EPA-approved pesticide master label. More specifically, the statement under the Brand Name of Product "Inovotabs Effervescent Tablets Only for use with Embrex in ovo vaccination devices" did not match the master label. The statement indicates that Inovotabs is to be used with a pesticide device, however, Inovotabs was not registered with the EPA to be used with a "vaccination device." In addition, the label did not include the statement "You may also contact [1-800-420-9236] for emergency medical treatment information."
- 8. The term "misbranded" as defined by Section 2(q) of FIFRA, 7 U.S.C. § 136 (q), includes labeling [which] bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular.
- 9. Because the cases of Inovotabs pesticide product are misbranded, the EPA denied the shipment and emailed a Notice of Refusal of Admission to Medentech and American that declined to allow the misbranded pesticide to be used, sold or distributed in the United States.
- 10. Pursuant to 19 C.F.R. § 12.112, the EPA is required to complete the ACE entry, indicating to CBP the disposition to be made of the shipment of pesticides upon its arrival in the United States. Based on the EPA's determination that the 1,200 cases are misbranded as described above, the EPA gave the shipment a Hold Intact status through the ACE System on May 15, 2018.
- 11. The "distribution or sale" of any pesticide which is misbranded is an unlawful act as pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

- 12. The term "to distribute or sell" as defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg) and 40 C.F.R. § 152.3, includes to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, or "release for shipment".
- 13. On July 2, 2018, Zoetis, a customer of the importer Medentech, emailed the EPA advising the EPA that the Inovotabs cases had been transported to Zoetis's facility in Marietta, Georgia, on May 15, 2018, and that 48 of the 1,200 cases had been shipped out to an end-use customer. Zoetis further advised that the remainder of the product cases, totaling 1,152 cases, were currently being held at the Zoetis Marietta Logistics Center located at 1950 West Oak Circle, Marietta, Georgia. Zoetis requested that it be allowed to re-label the 1,152 cases through the issuance of a SSURO, and that the relabeling would be conducted at Contrapac, Inc., an EPA-registered establishment (EPA Establishment Number 52270-GA-001), located at 675 Great Southwest Parkway, Atlanta, Georgia 30336.
- 14. On August 3, 2018, the licensed customs broker American submitted entry documents via the CBP's ACE Data Processing System on behalf of Medentech for the importation of one shipment of the pesticide product Inovotabs (EPA Reg. No. 71847-3-1007) which contained a total of one thousand two hundred (1,200) cases, each case weighing 4.81 kilograms. The Importer of Record in this matter is also Medentech.
- 15. The information provided to the EPA Region 4 through the CBP ACE System indicated that the shipment of Inovotabs was scheduled to arrive at the Port of Atlanta on July 29, 2018. On August 8, 2018, American notified the EPA the shipment is located at the Port of Charleston and not the Port of Atlanta.

- After reviewing the ACE entry, the EPA asked Medentech and American on August 3, 2018, to upload into the ACE system a legible copy of the label that was affixed to the 1,200 cases of the Inovotab pesticide product. On August 3, 2018, American uploaded the label but the EPA notified American by email that it was not a full label. On August 7, 2018, the EPA asked American to upload the full label, and on August 8, 2018, the EPA reviewed the ACE entry and determined that the label uploaded by American, which American had represented to be the label on the product cases, included incorrect information that was not compliant with the EPA master label for the product.
- 17. On August 9, 2018, the EPA Region 4 informed American by email that the label submitted for the Inovotabs pesticide product being imported by Medentech did not correspond with the pesticide's most current EPA-approved pesticide master label. On August 10, 2018, the EPA Region 4 informed American and Medentech that under the Step by Step Inovotabs Mixing Directions, the label does not contain step number 11, "Twist close plastic bag and close lid firmly after withdrawing tablets from container." In addition, the outer carton label does not make reference to the full tub label and contains the sentence "Contains: Anhydrous Sodium Dichloroisocyanurate...CAS NO. 2893-78-9" which is not on the master label.
- 18. Pursuant to 19 C.F.R. § 12.112, the EPA is required to complete the ACE entry, indicating to CBP the disposition to be made of the shipment of pesticides upon its arrival in the United States. Based on the EPA's determination that the 1,200 cases are misbranded as described above, the EPA gave the shipment a Hold Intact status through the ACE System on August 10, 2018.

19. The 1,152 cases of pesticide product Inovotabs that were shipped to the United States by Medentech, which arrived on April 27, 2018, that are in the possession of Zoetis and the 1,200 cases of pesticide product Inovotabs that were shipped to the United States by Medentech, which arrived on July 29, 2018, that are located at the Port of Charleston, as set forth in this SSURO, are misbranded and further sale or distribution of the 2,352 cases in the United States, including moving the product to an EPA-registered Producer Establishment for relabeling, by Zoetis, or Medentech or any other person, except in compliance with this SSURO and the requirements of FIFRA, would violate FIFRA.

#### II. ORDER

- 20. Zoetis is hereby ordered NOT to distribute, sell, use or remove any of the one thousand one-hundred fifty-two (1,152) cases of Inovotabs from the shipment that arrived at the Port of Charleston on or around April 27, 2018, that are currently being held at its facility in Marietta, Georgia, and the twelve-hundred (1,200) cases of pesticide product Inovotabs that arrived at the Port of Charleston on or around July 29, 2018, that are currently located at the Port of Charleston south terminal, except in compliance with FIFRA, and specifically, in compliance with one of the two options below:
  - a. The misbranded cases must either be exported out of the country or destroyed immediately in compliance with FIFRA;

OR

- b. Zoetis must take the following steps:
  - The misbranded cases must be properly relabeled in accordance with FIFRA requirements at Contrapac, Inc. located at 675 Great Southwest Parkway, Atlanta, Georgia 30336 (EPA Establishment Number 52270-

GA-001).

- ii. Within 48 hours after completion of relabeling, Zoetis must submit to the EPA pictures of the re-labeled cases along with a certification from the CEO of the company or another authorized official of the company stating that the re-labeling has been completed and is in compliance with the requirements of this SSURO and FIFRA.
- iii. The EPA may decide to conduct an inspection at Contrapac, Inc. to confirm and verify that the cases have been relabeled in compliance with this SSURO and FIFRA.
- 21. Zoetis shall not commence any sale, use, removal or distribution of the cases of Inovotabs unless: (1) Zoetis is in compliance with FIFRA and has taken all the actions required in Section II of this SSURO; and (2) the EPA has vacated this SSURO. All communications, including submission of photographs and the certification required above, should be directed to:

Kimberly Tomczak
Pesticides Section
U.S. EPA Region 4
61 Forsyth Street S.W.
Atlanta, Georgia 30303-8960
tomczak.kimberly@epa.gov
(404) 562-8987.

- 22. Violation of the terms or provisions of this SSURO may subject Zoetis to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 1361.
- 23. The issuance of this SSURO shall not act as a waiver by the EPA of any enforcement or other authority available to the EPA under FIFRA.
- 24. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by Zoetis.

- 25. This SSURO shall remain in effect until the EPA vacates the SSURO in writing.
- 26. The EPA may at any time amend this SSURO.
- Zoetis may seek judicial review of this SSURO pursuant to Section 16 of FIFRA,7 U.S.C. § 136n.

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Beverly H. Banister

Director

Air, Pesticides and Toxics Management Division



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

SEP 2 8 2018

# **UNITED PARCEL SERVICE**

Mr. Christopher Sebley Zoetis 1040 Swabia Court Durham, North Carolina 27703

Re: Case No: FIFRA-04-2018-3257

Amended Stop Sale, Use, or Removal Order

Dear Mr. Sebley:

This letter is amending the address and the establishment number of Contrapac, Inc., listed in the Stop Sale, Use or Removal Order (SSURO) that the U.S. Environmental Protection Agency issued on August 13, 2018, to Zoetis pursuant to the authority set forth in Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C.§ 136k. In the amended SSURO, the address and the EPA establishment number of Contrapac, Inc., has been changed to 5400 Bucknell Drive, Atlanta, Georgia 30036 (EPA Establishment Number 52770-GA-03). The enclosure is the amended SSURO, and is effective immediately.

Please contact Kimberly Tomczak of the EPA Region 4 staff at (404) 562-8987, or via email at tomczak.kimberly@epa.gov if you have any further questions regarding this amendment.

Sincerely

Anthony G. Toney

Chief

Chemical Safety and Enforcement Branch

**Enclosure** 

cc: Thomas Gray

Georgia Department of Agriculture

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IN THE MATTER OF:	) .	AMENDMENT to
Zoetis	)	STOP SALE, USE, OR
	)	REMOVAL ORDER
Respondent.	)	
	)	FIFRA-04-2018-3257
	)	

- On August 13, 2018, the U.S. Environmental Protection Agency Region 4 issued the above-captioned Stop Sale, Use, or Removal Order (SSURO) (FIFRA-04-2018-3257) to Zoetis. The SSURO authorized Zoetis to relabel a shipment of the misbranded pesticide product, Inovotabs (EPA Reg. No. 71847-3-1007), at Contrapac, Inc., an EPA-registered establishment located at 675 Southwest Parkway, Atlanta, Georgia 30036 (EPA Establishment Number 52270-GA-001).
- 2. On September 17, 2018, Zoetis' Associate Director contacted the EPA and stated that due to capacity issues at the Southwest Parkway Contrapac facility, Zoetis was requesting permission to have the relabeling take place at another Contrapac, Inc. facility located around the block at 5400 Bucknell Drive, Atlanta, Georgia 30036 (EPA Establishment Number 52270-GA-03).
- 3. Based on the foregoing, the EPA is amending the SSURO issued on August 13, 2018, as follows:
  - The address and EPA establishment number of Contrapac, Inc., noted in paragraphs 13 and 20 of the original SSURO as 675 Southwest Parkway, Atlanta, Georgia 30036 (EPA Establishment Number 52270-GA-001), are hereby changed to 5400 Bucknell Drive, Atlanta, Georgia 30036 (EPA Establishment Number 52770-GA-03).
  - ii. All other provisions of the SSURO issued on August 13, 2018, remain in full force and effect until the EPA vacates the SSURO.

1/27/17 Date

Beverly H. Banister

Director

Air, Pesticides and Toxics Management Division

# **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY THAT AN ORIGINAL OF THIS Amendment to the Stop, Sale, Use, and Removal Order, Docket Number: FIFRA-04-2018-3257 was sent certified mail/return requested and via UPS overnight mail to:

Mr. Christopher Sebley Zoetis 1040 Swabia Court Durham, North Carolina 27703 (via United Parcel Service)

Mr. Robert Caplan Senior Attorney Office of Regional Counsel U.S. EPA Region 4 61 Forsyth Street, S.W. Atlanta, Georgia 30303

DATE

(via EPA's internal mail)

Pamela A. Moultrie Staff Assistant U.S. EPA Region 4 61 Forsyth Street, S.W. Atlanta, Georgia 30303

(404) 562-9181

# Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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## FOR ANIMALS, FOR HEALTH, FOR YOU.

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, October 23, 2018 3:16 PM To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good afternoon,

I have reached out to my Supervisor in regards to this request and will get back in touch with you as soon as I can.

The shipment should remain where it is currently located until you hear back from the EPA Region 4 office.

Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly < Tomczak, Kimberly@epa.gov>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

Office. 209.309.9096 | Cell. 209.700.1241 | John.p.crane@zoeus.com

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# zoetis

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks!

Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

< ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

Thank you,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 101,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

# Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Bauman, Michael < <u>bauman.michael@epa.gov</u>>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

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Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

Thank you,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 101.562.8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks!

Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow.

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM

To: Bauman, Michael < bauman.michael@epa.gov > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

Visit Us: zoetis.com

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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com> Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM

To: Crane, John P < john.p.crane@zoetis.com >

Cc: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

#### Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

PHONE: 404,302,6367

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Harmer, Jennifer < jennifer.harmer@zoetis.com >

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a> Cc: Crane, John P < <a href="mailto:john.p.crane@zoetis.com">john.p.crane@zoetis.com</a> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

## Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com > Cc: Crane, John P < iohn.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Sebley, Christopher H < christopher.sebley@zoetis.com>; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

#### Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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# Tomczak, Kimberly

From:

Crane, John P <john.p.crane@zoetis.com> Wednesday, October 31, 2018 4:07 PM

Sent: To:

Tomczak, Kimberly

Cc:

Bauman, Michael; Ho, Kanoelehua; Harmer, Jennifer

Subject:

RE: Case No. FIFRA-04-2018-3257

Hi Kim:

I am off on vacation tomorrow until Nov 14 so Jennifer will be your contact now.

Thank you.

John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com
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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, October 31, 2018 4:03 PM **To:** Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

I am in discussions with my Supervisor about the steps that will need to be taken to get these shipments exported.

I will be in touch with you tomorrow or Friday.

## Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Tuesday, October 30, 2018 6:47 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Good morning Kimberly:

Are you able to advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Tuesday, October 23, 2018 3:33 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

Thank you for your message. We look forward to hearing back from you.



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

DEC 2 8 2018

# **UNITED PARCEL SERVICE**

Mr. John P. Crane Director, U. S. Regulatory Affairs Zoetis 333 Portage Street Kalamazoo, Michigan 49007

> Re: Case No: FIFRA-04-2018-3257 Stop Sale, Use, or Removal Order

Dear Mr. Crane:

The U.S. Environmental Protection Agency was notified by Zoetis, that Medentech has requested to export the two shipments, under Entry Numbers U16-10064192 and U16-10084042, listed in the Stop Sale, Use, or Removal Order (SSURO) that the EPA issued on August 13, 2018, to Zoetis pursuant to the authority set forth in Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C.§ 136k. On October 22, 2018, Zoetis notified the EPA Region 4 that Medentech has decided to export the two shipments back to their facility in Ireland, to be relabeled or repackaged. The EPA Region 4 is hereby allowing Medentech to export the products back to a Medentech facility in Ireland. In order to vacate the SSURO, issued on August 13, 2018, we require verification that the shipment has been received at Medentech. Therefore, please send a letter confirming that the product has been exported to, and received at Medentech in Ireland.

Please contact Kimberly Tomczak of the EPA Region 4 staff at (404) 562-8987, or via email at tomczak.kimberly@epa.gov if you have any further questions regarding this letter.

Sincerely,

Kimberly L. Bingham

Chief

**Pesticides Section** 



Ms. Kimberly L. Bingham, Chief Pesticides Section US EPA Region 4 Atlanta Federal Center 61 Forsyth Street, Atlanta, GA 30303-8960

RE: Case No. FIFRA-04-2018-3257, Stop Sale, Use, or Removal Order

Dear Ms. Bingham,

Zoetis is in receipt of the letter dated 28 December 2018 regarding the Stop Sale Use and Removal Order (Case No. FIFRA-04-2018-3257) for two shipments of INOVOTABS (Entry Numbers U16-10064192 and U16-10084042). In the letter, the EPA notified Zoetis that Medentech was allowed to export the products back to the Medentech facility in Ireland. Further, the letter stated that in order to vacate the SSURO, issued on 13 August 2018, Zoetis is required to verify that the shipments have been received at Medentech.

Zoetis hereby confirms that the two shipments have been exported to, and received by, Medentech in Ireland.

Zoetis looks forward to receiving notification from the EPA that the SSURO has been vacated.

If there are any questions or concerns regarding this notice, please contact me at (269) 359-4857 or jennifer.harmer@zoetis.com.

Regards,

Jennifer C. Harmer

Associate Director, Regulatory Affairs

fu CHam

cc: Julie Lambert, Head of Technical and Quality, Medentech



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

MAY 1 5 2019

# **UNITED PARCEL SERVICE**

Ms. Jennifer C. Harmer Zoetis Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street Kalamazoo, Michigan 49007

Re: Case No: Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA-04-2018-3257)
Termination Letter of Stop Sale, Use, or Removal Order

Dear Ms. Harmer:

The U.S. Environmental Protection Agency has terminated the Stop, Sale, Use, or Removal Order, that was issued to Zoetis on August 13, 2018, pursuant to Section 13 of FIFRA. The enclosed Termination is effective immediately.

Please contact Kimberly Tomczak at (404) 562-8987, if you have any further questions regarding this Vacatur.

Sincerely.

Larry L. Lamberth

Chief, Chemical Safety and Land Enforcement

Branch

Enforcement Compliance and Assurance Division

Enclosure

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 4 ATLANTA, GEORGIA

IN THE MATTER OF:	)
	) TERMINATION OF
Zoetis	) STOP SALE, USE, O
Respondent.	) REMOVAL ORDER
	)
	) FIFRA-04-2018-3257
	)

# TERMINATION OF STOP SALE, USE, OR REMOVAL ORDER

- 1. On August 13, 2018, the U.S. Environmental Protection Agency Region 4, issued a Stop Sale, Use, or Removal Order (SSURO), FIFRA-04-2018-3257, to Zoetis, pursuant to Section 13 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prohibiting the sale, use, or removal of 1.152 cases of the pesticide product Inovotabs (EPA Reg. No. 71847-3-1007) that were shipped to the United States by Medentech, which arrived on April 27, 2018, and 1,200 cases of Inovotabs that were shipped to the United States by Medentech, which arrived on July 29, 2018. The Importer of Record in this matter is Medentech, a business located at Whitemill Industrial Estate. Wexford, Ireland.
- 2. Based on its review of the labels on the cases of the Inovotabs product, the EPA Region 4 determined that the cases were misbranded and in violation of FIFRA. The SSURO ordered Zoetis not to distribute, sell, use, or remove the cases of the pesticide product Inovotabs, except in compliance with the requirements of the SSURO and FIFRA.
- In response to, and as allowed by the SSURO issued on August 13, 2018, Zoetis relabeled the
  cases of the pesticide product Inovotabs at Contrapac, Inc. located at 5400 Bucknell Drive,

Atlanta, Georgia 30036 (EPA Establishment Number 52770-GA-03). On October 22, 2018, Zoetis notified the EPA that the cases of the pesticide product were relabeled incorrectly. Zoetis advised the EPA that Medentech had requested to export the two shipments, under Entry Numbers U16-10064192 and U16-10084042 back to its facility in Ireland.

- 4. On December 28, 2018, the EPA issued a letter to Zoetis which stated that the two shipments could be exported back to Medentech's facility in Ireland, and that in order to terminate the SSURO, Zoetis would need to submit a letter to the EPA confirming that the product had been exported to, and received at Medentech in Ireland.
- On April 3, 2019, the EPA received a letter from Zoetis stating that the two shipments, under Entry Numbers U16-10064192 and U16-10084042, have been exported to, and received by Medentech in Ireland.
- 6. In view of Zoetis and Medentech having exported the two shipments back to Medentech in Ireland, the SSURO is hereby TERMINATED.
- 7. The issuance of this Termination of SSURO shall not act as a waiver by the EPA of any enforcement action that may be brought against Zoetis for violations of FIFRA in connection with the import of the pesticide products, as set forth in the SSURO and herein, or for any future enforcement actions or other authority available to the EPA under FIFRA.
- 8. This Termination is effective upon the date it is signed by the EPA official designated below.

MAY 1 5 2019

DATE

Suzanne G. Rubini

**Acting Director** 

Enforcement and Compliance Assurance Division

From: Bingham, Kimberly

Sent: Monday, May 14, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10064192

I am fine with denying the shipment. KLB

Kimberly L. Bingham, MPH | Chief, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Voice: 404-562-9038 | Email: bingham.kimberly@epa.gov

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From: Tomczak, Kimberly

Sent: Monday, May 14, 2018 2:07 PM

To: Bingham, Kimberly < Bingham. Kimberly@epa.gov>

Cc: Bauman, Michael <br/>
<br/>
dauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>

Subject: Entry Number U16-10064192

# \*For Deliberative Purposes Only\*

Kimberly,

Please see the below:

Description: Entry Number: Registered product U16-10064192

Port of Entry:

Charleston, South Carolina

Released:

April 30, 2018

Recommended Action: Deny; Notice of Refusal

#### <u>Product(s) Information</u> (Name, Product type, Signal Word, No. of containers and Total Net weight):

- INVOTABS
  - 1200 containers, each container is 4.81 KG, 1544.00 KG total

#### **Specific Information:**

- Imported product label does not match the EPA Master Label.
  - a. The statement under the Brand Name of Product (Inovotabs Effervescent Tablets Only for use with Embrex in ovo vaccination devices) does not match the master label.
  - b. The label does not include the statement "You may also contact [1-800-420-9236] for emergency medical treatment information."
- I emailed the Product Manager and she said an amendment would need to be made to correct the issue.

I recommend that we deny this product.

Please let me know how I should proceed.

## Regards,

Knoberly Tomczak, Lile Scientis; US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsvili St. SW Adama, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Miguel Rivera [mailto:mrivera@AmericanCargoExpress.com]

Sent: Monday, May 14, 2018 9:39 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10064192

Dear Kimberly,

Please note attached that I will load in DIS shortly. This is the exact label that is on the product.

Thank you, Miguel Rivera Echo Customs Entry

#### **ACE USA & CANADA**

American Cargo Express
New Jersey Operations
2345 Vauxhall Rd
Union, NJ 07083
Tel: 908-351-3400 x 3050

Tel: 908-351-3400 x 3050 Fax: 908-289-2490

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Friday, May 11, 2018 6:58 AM

To: Miguel Rivera; 'AHANLEY@MEDENTECH.COM'

**Cc:** Bauman, Michael; Ho, Kanoelehua **Subject:** RE: Entry Number U16-10064192

Good morning,

Are the labels that were uploaded to the DIS Docs, the labels that are on the product at the port?

The labels uploaded to the DIS Docs do not match the EPA master label. More specifically, the statement under the Brand Name of Product does not match the master label and the label does not include the statement "You may also contact [1-800-420-9236] for emergency medical treatment information."

## Please advise if the labels uploaded are the labels that are on the product at the port. Thank you.

#### Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 104.562.8987

Email: Tomczak.kimberly@epa.gov

From: Tomczak, Kimberly

Sent: Thursday, May 10, 2018 11:13 AM

To: 'Miguel Rivera' < mrivera@AmericanCargoExpress.com'>; 'AHANLEY@MEDENTECH.COM'

<AHANLEY@MEDENTECH.COM>

Subject: RE: Entry Number U16-10064192

Hi Miguel,

Can you upload the label (to the DIS Docs) that contains the Batch Number?

Please upload the label by COB today. Thank you.

#### Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Allanta, GA 30303 Phone: 401,562,8987 Email: Tomczak.kimberly@epa.gov

From: Tomczak, Kimberly

Sent: Tuesday, May 08, 2018 2:32 PM

To: 'Miguel Rivera' <mrivera@AmericanCargoExpress.com>; 'AHANLEY@MEDENTECH.COM'

<AHANLEY@MEDENTECH.COM>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10064192

Hi Miguel,

Can you upload the label (to the DIS Docs) that contains the Batch Number? Thank you.

# Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atkana, GA 30303.

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Miguel Rivera [mailto:mrivera@AmericanCargoExpress.com]

Sent: Tuesday, May 08, 2018 9:29 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10064192

Good morning,

Please note below from the customer.

Once a batch of tablets has been produced for your order, the batch number is reserved to our electronic system. The product is then scheduled into production, the batch and expiry details are printed onto the tub labels and outer labels prior to tub application.

All details are recorded onto batch records which are stored for each specific customer in accordance with HPRA (Irish health Products Authority) regulations.

Our company is also fully GMP, ISO compliant. Let me know if you need anything further.

Kind Regards

Nicola

Thank you, Miguel Rivera Echo Customs Entry

#### **ACE USA & CANADA**

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Fax: 908-289-2490

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From: Miguel Rivera

**Sent:** Monday, May 7, 2018 3:35 PM

To: 'Tomczak, Kimberly'; AHANLEY@MEDENTECH.COM

**Cc:** Bauman, Michael; Ho, Kanoelehua **Subject:** RE: Entry Number U16-10064192

Hi Kimberly.

I will have an answer for you shortly I have requested the information from the customer.

Thank you, Miguel Rivera Echo Customs Entry

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Fax: 908-289-2490

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From: Tomczak, Kimberly [mailto:Tomczak,Kimberly@epa.gov]

Sent: Monday, May 7, 2018 11:13 AM

To: Miguel Rivera: AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael; Ho, Kanoelehua Subject: RE: Entry Number U16-10064192

Hi Miguel,

The label States "B/No: XXXX". My question is, when is the exact Batch Number added to the product label At what stage in production is the lot/batch number added to the label/container?

### Regards,

Kimberly Comezak, Life Scienast US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Adamia, GA 30303 Phone: 101,562,8987

Email: Tomczak.kimberly@cpa.gov

From: Miguel Rivera [mailto:mrivera@AmericanCargoExpress.com]

Sent: Monday, May 07, 2018 11:08 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10064192

Good morning,

I am not sure I understand your question?

Thank you, Miguel Rivera Echo Customs Entry

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, May 7, 2018 10:59 AM

To: Miguel Rivera; AHANLEY@MEDENTECH.COM

**Cc:** Bauman, Michael; Ho, Kanoelehua **Subject:** RE: Entry Number U16-10064192

Hi Miguel,

I see that the exact batch number wasn't included on the first label submitted. At what stage in production is the lot/batch number added to the label/container?

Thank you.

Regards,

From: Tomczak, Kimberly

**Sent:** Friday, May 04, 2018 8:49 AM

To: 'Miguel Rivera' <mrivera@AmericanCargoExpress.com>; 'AHANLEY@MEDENTECH.COM'

<AHANLEY@MEDENTECH.COM>

Subject: RE: Entry Number U16-10064192

Hi Miguel,

The label that you uploaded is still blurry. In order to process the entry, I will need to review a legible label.

Please upload a legible label by COB today, else the entry will have to be denied. Thank you.

Regards,

From: Tomczak, Kimberly

Sent: Thursday, May 03, 2018 7:11 AM

To: 'Miguel Rivera' < mrivera@AmericanCargoExpress.com'>; AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael < bauman.michael@epa.gov'>; Ho, Kanoelehua@epa.gov'>

Subject: RE: Entry Number U16-10064192

Hi Miguel,

The label that you uploaded is still blurry. In order to process the entry, I will need to review a legible label.

Please upload a legible label by COB today. Thank you.

Regards,

From: Miguel Rivera [mailto:mrivera@AmericanCargoExpress.com]

Sent: Wednesday, May 02, 2018 11:25 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10064192

Hello.

Well noted but they will come out a little blurred as they did the 1st time.

Thank you, Miguel Rivera Echo Customs Entry

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, May 2, 2018 11:21 AM

To: Miguel Rivera; AHANLEY@MEDENTECH.COM

**Cc:** Bauman, Michael; Ho, Kanoelehua **Subject:** RE: Entry Number U16-10064192

## Good morning,

Please upload the label to the DIS Docs. Thank you.

## Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region & Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Miguel Rivera [mailto:mrivera@AmericanCargoExpress.com]

Sent: Wednesday, May 02, 2018 11:19 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>>, Ho, Kanoelehua <a href="mailto:kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>>

Subject: RE: Entry Number U16-10064192

Good morning,

Please note attached

Thank you. Miguel Rivera Echo Customs Entry

## **ACE USA & CANADA**

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Fax: 908-289-2490

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, May 2, 2018 11:04 AM

To: Miguel Rivera; AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael; Ho, Kanoelehua Subject: RE: Entry Number U16-10064192

Good morning,

The label you uploaded is not legible.

# Please upload a legible label by COB today. Thank you.

## Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 104,562,8987

Fmail: Tomczak.kimberly@epa.gov

From: Miguel Rivera [mailto:mrivera@AmericanCargoExpress.com]

Sent: Wednesday, May 02, 2018 9:41 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; AHANLEY@MEDENTECH.COM

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10064192

Good morning,

Documents have been submitted, please note attached.

Thank you, Miguel Rivera Echo Customs Entry

### **ACE USA & CANADA**

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Fax: 908-289-2490

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**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, May 2, 2018 7:00 AM

To: Miguel Rivera; AHANLEY@MEDENTECH.COM

**Cc:** Bauman, Michael; Ho, Kanoelehua **Subject:** RE: Entry Number U16-10064192

Good morning,

A reminder that Entry Number U16-10064192 was given a Hold Intact because the label was not uploaded to the DIS Docs.

## Please upload the label within two business days. Thank you.

## Regards,

Kimberly Tomczak, Life Scienust US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adanta, GA (2030) Phone: 404.562.8987 Email: Tomczak.kimberly@cpa.gov

From: Tomczak, Kimberly

Sent: Tuesday, May 01, 2018 8:31 AM

To: 'MRIVERA@AMERICANCARGOEXPRESS.COM' < MRIVERA@AMERICANCARGOEXPRESS.COM';

'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: Entry Number U16-10064192

Good morning,

Entry Number U16-10064192 was given a Hold Intact because the label was not uploaded to the DIS Docs.

Please upload the label within three business days. Thank you.

### Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Adama, GA 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

# Tomczak, Kimberly

From:

MARTINEZ, ESMERALDA < ESMERALDA.MARTINEZ@cbp.dhs.gov>

Sent:

Wednesday, July 25, 2018 1:50 PM

To:

Tomczak, Kimberly

Subject:

RE: Entry # U16-10064192

## Perfect! Thanks!

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, July 25, 2018 10:27 AM

To: MARTINEZ, ESMERALDA < ESMERALDA.MARTINEZ@cbp.dhs.gov>

**Subject:** RE: Entry # U16-10064192

Good afternoon,

Yes, I can provide you with a copy of the Stop, Sale Order and Vacatur letter.

## Thank you,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GÁ 30303 Phone: 404,562,8987

1 1010. 101. 012.0.007

Email: Tomczak,kimberly@epa.gov

From: MARTINEZ, ESMERALDA [mailto:ESMERALDA.MARTINEZ@cbp.dhs.gov]

Sent: Wednesday, July 25, 2018 1:24 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Thank you for the update Kimberly. Once the relabeling is completed, will you providing a letter response to the Importer? If so, can you provide me with a copy and I will closed with compliance.

Thank you,

# Esmeralda Martinez

Entry Specialist (Team 091)
U.S. Customs and Border Protection
Pharmaceuticals, Health & Chemicals Center



9777 Via De La Amistad San Diego, CA 92154 <u>esmeralda.martinez@cbp.dhs.gov</u> Office (619) 671-8040 | Fax (619) 661-3178

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, July 25, 2018 9:59 AM

To: MARTINEZ, ESMERALDA < ESMERALDA.MARTINEZ@cbp.dhs.gov >

**Subject:** RE: Entry # U16-10064192

Good afternoon,

Thank you for your assistance.

We will be issuing a Stop, Sale Order for Entry U16-10064192. Once the Order has been issued, we will allow the company to move the shipment to a EPA registered establishment to be relabeled.

Please let me know if you have any questions.

## Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: MARTINEZ, ESMERALDA [mailto:ESMERALDA.MARTINEZ@cbp.dhs.gov]

Sent: Tuesday, July 24, 2018 12:56 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: GENNA, CARRIE < CARRIE.GENNA@cbp.dhs.gov>

Subject: RE: Entry # U16-10064192

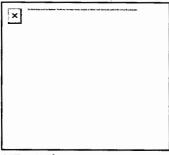
Hello Kimberly,

Yes, the Port of Charleston can extend the end date. We are always more than willing to work with the broker/importer with their compliance efforts. Let me know if you have any other questions.

Respectfully,

# Esmeralda Martinez

Entry Specialist | Enforcement (Team 091)
Pharmaceuticals, Health & Chemicals Center



NTEU Chapter 105 Area VP/ Chief Steward Non-Uniform Personnel esmeralda.martinez@cbp.dhs.gov | esmeralda.martinez@nteu105.org Office (619) 671-8040 | Fax (619) 661-3178

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, July 24, 2018 9:44 AM

To: MARTINEZ, ESMERALDA < ESMERALDA. MARTINEZ@cbp.dhs.gov>

Cc: GENNA, CARRIE < CARRIE.GENNA@cbp.dhs.gov>

**Subject:** RE: Entry # U16-10064192

Good morning Officer Martinez,

Would CBP at the Port of Charleston be able to extend the end date for Entry U16-10064192?

Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 101.562.8987

Email: Tomczak.kimberly@epa.gov

From: GENNA, CARRIE [mailto:CARRIE.GENNA@cbp.dhs.gov]

**Sent:** Monday, July 23, 2018 7:57 AM

To: MARTINEZ, ESMERALDA < ESMERALDA. MARTINEZ@cbp.dhs.gov>

Cc: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Subject:** FW: Entry # U16-10064192

Importance: High

There is a VA assigned to you on this entry. Can you please advise EPA and the customs broker how to proceed.

Thank you, CBPO Carrie Genna Cargo Release Team **U.S.**Customs and Border Protection 200 East Bay street Charleston, SC 843-**5**79-6535 Carrie.genna@cbp.dhs.gov Or 1601cargorelease@cbp.dhs.gov

From: Tomczak, Kimberly < Tomczak. Kimberly @epa.gov>

**Sent:** Friday, July 20, 2018 12:18 PM

To: GENNA, CARRIE < CARRIE.GENNA@cbp.dhs.gov>

**Subject:** FW: Entry # U16-10064192

Importance: High

Good afternoon,

If we issue a Stop, Sale order for Entry U16-10064192, would CBP at the Port of Charleston be able to extend the end date? See email below.

## Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adama, GA 30303 Phone: 101,562,8987

Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 19, 2018 9:26 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Subject: FW: Entry # U16-10064192

Importance: High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

## Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

## FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 3:11 PM

To: Tomczak.kimberly@epa.gov

Cc: Bucher, Art

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

I was checking the EPA registry and found that the site currently storing the product in question is EPA registered. Is this sufficient to complete the re-labelling here?

## Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct. Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

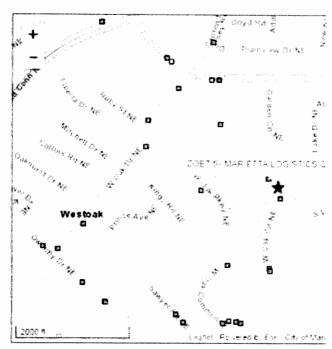
# zoetis

## FOR ANIMALS, FOR HEALTH, FOR YOU.

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# **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id: 110070021744 1950 WEST OAK CIRCLE MARIETTA, GA 30062



# Legend

- Selected Facility
- EPA Facility of Interest
- □ State/Tribe Facility of Interest

The facility locations displayed come from the FRS Spatial Coordinates tables. They are the best representative locations for the displayed facilities based on the accuracy of the collection method and quality assurance checks performed against each location. The North American Clarum of 1985 is used to display, all coordinates.

# Facility Registry Service Links:

- Easility Registry Service (LES) Sherview
- FRS Facility Duery
- EBS Organization Space
- EZ Jugayy
- FBS Physical Cars Model
- TRS Georganiai Model



#### **Environmental Interests**

Information System	Soutem Excility Name	Information System Id/Report Link	Environmental Interest Type	Chata Spurce	Date	Supplemental Emer
MATIONAL TO LITTERY DESCRIPTION SIZEMENTATION	ZOETIS- MARIETTA LOGISTICS CENTER		STORM WATER INDUSTRIAL	1015		
VATIONA, ACCUSANT CONTRAPTS ( DEEMS IN )	COETIS MARCETTA	9454976	ICIS-NPOES TROTI	1015		

	Stan	dard Industrial Classification Codes (SIC)	
Data Scarce	SK: Code	Description	Primary
NPDES	4225	GENERAL WAREHOUSING AND STORAGE	
		Facility Codes and Flags	
CPA Region		04	National Industry Classification System Codes (NAICS)
Duns Number			Michael Hanny Company Street Company
Congressional	Destrict Numbe	f 26	No NAIGS Codes returned.
Legislatore (No	Ingi Mumber		
HUC Code/Wat	esshed.	03130001 / UPPEP CHATTAHOOCHES	Facility Mailing Addresses
US Mesuca Boro	der indicator		No Facility Maring Accresses returned.
Federal Facility	!		HOLLEDICK HANNY HOSTERSED SECTIONED.
Enhal Land			Contacts

he Contacts returned

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 8:49 AM

To: 'Tomczak, Kimberly'

**Subject:** RE: Entry # U16-10064192

Kimberly,

I have located a company that will re-label the product in the Atlanta area.

PCA –Atlanta 6300 Boat Rock Blvd Suite E Atlanta, GA 30336

It is 24 miles from the current warehouse in Marietta GA (Zoetis Marietta Logistics Center, 1950 West Oak Circle, Marietta, GA) where the product is located. They will apply to become an EPA registered site to perform this work.

Please let me know as soon as you can if this acceptable. If not I need to start the export process as Customs has a dead line of 7/28/18 for this material to leave the country.

Regards,

Chris Sebley | Senior Manager. Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA -

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:12 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

Unfortunately, the product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

# Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303

Phone: 104.562.8987

Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

## Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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# zoetis

## FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:00 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

## Good afternoon,

The product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

## Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section

61 Forsyth St. SW Adamta, GA 30303

Phone: 401.562.8987

Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 2:58 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

Zoetis has a site in Kalamazoo MI that I have been told is an EPA registered site. I will find out the details and send them to you.

## Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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Please consider the environment before printing this email! Thank you.

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 2:10 PM

**To:** Sebley, Christopher H **Cc:** Doireann O'Brien

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

## Hi Christopher,

If we were to allow you to relabel the product, where would the relabeling take place? The product would need to be relabeled in a EPA Registered Establishment.

Thank you,

Kimberly Tomezak, Life Scientist

US Environmental Protection Agency, Region 1

Pesticides Section:

61 Forsyth St. SW Atlanta, GA 20303.

Phone, 104,562,8987

Final: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

Subject: Re: Entry # U16-10064192

Kimberly,

We would get enough labels from the manufacturer that match the master label you have on file. They have revised the label recently to ensure they match.

Regards, Chris Sebley

Sent from my iPhone

On Jul 11, 2018, at 8:38 AM, Tomczak, Kimberly <Tomczak.Kimberly@epa.gov> wrote:

NOTICE: This message originates from an external source.

Hi Chris,

If we allowed you to relabel this product, would you relabel using the last EPA registered label?

Or were you looking to make a notification/amendment change to revise the label?

Thank you,

Kimberly Tomczak, Life Scientisi US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Finail: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

Subject: Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > wrote:

NOTICE: This message originates from an external source.

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kumberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 64 Forsyth St. SW Adanta, GA 30303 Phone: 404.562.8987 Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL TABLETS

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 – 40HC DESTINATION – CHARLESTON, SC

1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been

placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.

2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

Regards,

Chris Sebiey | Senior Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

<image001.gif>

Please consider the environment before printing this email! Thank you.

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 30, 2018 8:04 AM **To:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Sections

61 Forsvih St. SW Atlanta, GA 30303.

Phone: 101.562.8987

tanaib Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kimberty Tomezak, Life Scienust US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 5930.3 Phone: 404,562,8987 Envail: Tomezak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

## Regards,

Kimberly Toniczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30305

Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>
Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section

61 Forsyth St. SW Atlanta, GA 30303

Phone: 104,562,8987

Final: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

## Regards,

Kimberly Toniczak, Life Scientis, US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30503 Phone: 404,562,8987 Email: Tomczak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<imessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 jennifer.harmer@zoetis.com

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Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks!
Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM

To: Crane, John P < john.p.crane@zoetis.com >

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

## Regards,

Kimberly Tomezak, Life Scients: US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30363 Phone: 104,562,8987 Email: Tomezak,kimberly@epa.gov From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

Regards,

Kimberly Tomczak, Lile Scientist US Environmental Protection Agency, Region 4 Pesticides Section

61 Forsyth St. SW Adams, GA 30303

Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269 359 9098 | Cell: 269 760 1241 | John p.

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kimberly Tourczak, Life Scientisi US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adama, GA 30303 Phone: 404.562.8987

Finail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

## Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,362,8987

Linail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a> Cc: Crane, John P < <a href="mailto:john.p.crane@zoetis.com">john.p.crane@zoetis.com</a> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

Regards,

Kimberly Tomezak, Late Scientist US Environmental Protection Agency, Region 1 Pesticides Section: 61 Forsyth St. SW Atlanta, GA 20303

Phone: 194,562,8987

Imail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

**Sent:** Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com> Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17th with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20th for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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61 Forsyth Street, SW Atlanta, GA 30303 | Voice: 404-562-9038 | Email: bingham.kimberly@epa.gov

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From: Tomczak, Kimberly

Sent: Tuesday, October 23, 2018 7:12 AM

To: Bingham, Kimberly < Bingham. Kimberly@epa.gov >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: FW: Case No. FIFRA-04-2018-3257

Kimberly,

Zoetis notified me that they would like to now export the shipments that are included in the SSURO.

Since they no longer wish to relabel, how do we close out of the SSURO? In addition, it may now be over 90 days, so can we pursue a penalty action?

## Regards,

Kimberly Tomezak, Life Scienist US Finvironmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<<u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks! Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>>; Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

Thank you,

Kumberly Tomezak, Life Scienist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 104,562,8987 Email: Tomezak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good afternoon,

# What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

# Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region † Pesticides Section 61 Forsyth St. SW Atlanta, GA 30363

Phone: 104,562,8987

Final: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Bauman, Michael < bauman.michael@epa.gov >

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < <a href="mailto:john.p.crane@zoetis.com">john.p.crane@zoetis.com</a>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

# Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region I Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>

Cc: Crane, John P < john.p.crane@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

# Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow.

Regards,

#### Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM
To: Bauman, Michael < bauman.michael@epa.gov > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 30, 2018 9:09 AM **To:** Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

# Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

# Regards,

Kumberly Tomezak, Life Scienist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

**To:** Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 30, 2018 8:04 AM **To:** Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

# Regards,

Kumberly Tomczak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section: 64 Forsyth St. SW Affanta, GA 20204 Phone: 101,562,8987

Final: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov> Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

# Regards,

Kimberly Tomczak, Life Scienust US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

# Regards,

Kimberly Tomczak, Life Scientis: US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Famil: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

# Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Adama, CACO303

Phone: 101.562.8987

Limit: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

#### Jennifer

Jennifer C. Harmer Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < <a href="mailto:christopher.sebley@zoetis.com">christopher.sebley@zoetis.com</a>; James Messina

<imessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

#### Regards,

Kimberty Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsvili St. SW Adams, GA 30303

Phone: 101,562,8987

Linail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<imessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

# Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly <Tomczak, Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

**Sent:** Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

**Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks! Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

# Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

#### Thank you,

Kimberly Fornezak, Life Scientist US Fuvironmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adanta, GA 30308 Phone: 404,562,8987

rnonc: 491.002.8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

Regards,

Kimberly Tomezak, Life Scienist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adama, GA 30303 Phone: 104,562,8987

1-mail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com> Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

Thank you,

Kimberly Tomczak, Life Scienust US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

**Sent:** Monday, September 17, 2018 11:54 AM **To:** Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow.

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM

To: Bauman, Michael < bauman.michael@epa.gov >
Cc: Crane, John P < john.p.crane@zoetis.com >
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling

operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 30, 2018 9:09 AM **To:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<<u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

#### Regards,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Adanta, GA 30303 Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

**Subject:** RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane Director, US Regulatory Affairs Visit Us: zoetis.com



# FOR ANIMALS, FOR HEALTH, FOR YOU.

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM

To: Crane, John P < john.p.crane@zoetis.com >

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

# Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30000

Phone: 404,562,8987

Email: Tomczak.kimberly@cpa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Harmer, Jennifer < jennifer.harmer@zoetis.com >

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a> Cc: Crane, John P < <a href="mailto:john.p.crane@zoetis.com">john.p.crane@zoetis.com</a> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kimberly Toniczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section

61 Forsyth St. SW Adama, GA 00303

Phone: 404.562.8987

Untail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < <a href="mailto:john.p.crane@zoetis.com">john.p.crane@zoetis.com</a>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section of Forsyth St. SW Atlanta, GA 30302 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com> Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com > Cc: Crane, John P < john.p.crane@zoetis.com> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adanta, GA 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<imessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

# Regards,

Kumberly Tomczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Final: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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# Tomczak.kimberly@epa.gov

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From: Nicola Roche < nicola.roche@kersia-group.com > Sent: Wednesday, December 19, 2018 10:28 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>;

ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: U16-10064192 and U16-10084042

Hi Kimberly,

I have been advised by the ACE director of import, that there is a discrepancy with regard to the attached letter.

The entry numbers U16 1006419-2 and U16-1008404-2 must appear on the letter along with our company name, Medentech as the exporter of the goods.

I understand that it is not your area, but I would sincerely appreciate that between yourself and Esmeralda I can be guided on this matter.

Everyone seems to have their own procedure and I just want to get move the goods with the correct documentation.

My sincere apologies. Nicola

Wicola ROCHE

Costratos frenzasor el Comone combon d'amogen

THE STATE OF THE S

From: Patti Cordo <pcordo@americancargoexpress.com>

Sent: Wednesday 19 December 2018 14:58

**To:** Jerina Morris < <u>imorris@AmericanCargoExpress.com</u>>; Nicola Roche < <u>nicola.roche@kersia-group.com</u>>; Greg Low < <u>greglow@comcast.net</u>>

**Cc:** Sinead Walsh < sinead.walsh@kersia-group.com >; Debra Fierro

<<u>dfierro@contrapac.com</u>>; Peter Fierro <pfierro@contrapac.com>; Mark Leonard

<Mark.Leonard@hornerd.ie>

Subject: RE: RETURN TO IRELAND -MEDENTECH

Nicola

What are you doing to rectify the discrepancy that the Customs Entry and the EPA letter?

Did you speak to EPA to get this corrected?

This is a huge problem as the notice of redelivery issued by Customs is passed date and the EPA letter is not to Medentech

Nor does it reference an entry number. This must be resolved prior to export

Regards, Patti

Patti Cordo

Director of Import ACE USA & Canada American Cargo Express New Jersey Operations 2345 Vauxhall Rd Union, NJ 07083 Tel: 908-351-3400 x 3026

Tel: 908-351-3400 X 302

Fax: 908-289-2490

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From: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

**Sent:** Tuesday 18 December 2018 17:18 **To:** ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>; Nicola Roche <nicola.roche@kersia-group.com>

Subject: U16-10064192 and U16-10084042

Importance: High

Good afternoon,

The importer for Entry U16-10064192 and U16-10084042 has decided to export these shipments. We had communicated earlier this year about these shipments (see emails on July 25, 2018).

The attached letter allows the company to export the products. Can you provide information to the broker on what other documents are needed to export the two shipments? The broker has been copied on the email.

# Thank you for your assistance,

for the control of the second of the control of the

From: Nicola Roche < nicola.roche@kersia-group.com >

Sent: Monday, December 17, 2018 11:34 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: FIFRA-04-2018-3257

Importance: High

Good afternoon Kimberly, I hope my mail finds you well.

This query is with regard to FIFRA-04-2018-3257.

We have been trying to consolidate both consignments into a high cubed container to return the goods as promptly as possible to Medentech.

However, the export company used by our carriers have advised that we can only move the goods under CBP supervision. The attached CBP form is related to the first shipment.

I have forwarded your attached letter of release and advised supervision is not required. The export company believes I need additional clearance from the EPA and at this point I really do not know what that is.

I sincerely apologise for contacting you, but if you can help at all I would be extremely grateful.

My very best regards Nicola

> Woofs ROCHE Costone Rushen & Communication Sanager sucotauroche@worstr group.com W/+450 sa sos 3000 - 1/+353 53 911 7929

From: Mark Leonard < Mark.Leonard@hornerd.ie >

**Sent:** Monday 17 December 2018 15:42

To: Nicola Roche <nicola.roche@kersia-group.com>; Neil Horner

<Neil.Horner@hornerd.ie>

**Cc:** Sinead Walsh < sinead.walsh@kersia-group.com > **Subject:** RE: RETURN TO IRELAND -MEDENTECH

Hi Nicola,

our agents have advised:

"this is rejected Merchandise to be returned under CBP supervision Note you will need to contact Nicola Roche at Medentech see attached Until Medentech have resolved the outstanding issues we cannot proceed with the Return

Thanks

Kind Regards, Mark.

<image002.png>

#### **HORNER AGENCIES LTD.,**

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<ACE SLI -revised Aug2018.xls>

<Case No FIFRA-04-2018-3257.pdf>

# Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Friday, July 06, 2018 10:52 AM

To:

Tomczak, Kimberly

Cc:

Doireann O'Brien

Subject:

Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly <a href="mailto:Tomczak.Kimberly@epa.gov">Tomczak.Kimberly@epa.gov</a>> wrote:

NOTICE: This message originates from an external source.

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region I Pesticides Section 64 Vorsyth St. SAV Atlanta, CA 30303 Phone: 40 EJ62.8987

Laval: Tomczak.kimberly@cpa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL TABLETS

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

- 1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.
- 2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

<image001.gif>

Please consider the environment before printing this email! Thank you.

# Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Thursday, July 12, 2018 3:34 PM

To:

Tomczak, Kimberly

Subject:

Re: Entry # U16-10064192

Kimberly, Let me look into this and get back to you. Regards, Chris Sebley

Sent from my iPhone

On Jul 12, 2018, at 3:12 PM, Tomczak, Kimberly < Tomczak. Kimberly@epa.gov > wrote:

NOTICE: This message originates from an external source.

Hi Chris,

Unfortunately, the product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

# Regards,

Kumberly Temezak. Like Scienist US Faivinouncemat Protection Agency, Region 4 Pesticides Section of Forsyth St. SAV Athania, GA 30303 Phone: 404.562.8987 Limit: Tomezak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

<image001.gif>

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:00 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE. This message originates from an external cource.

# Good afternoon,

The product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

# Regards,

Kiroberte Lomezak, late Scientia US Envarantiemal Protection Agency Region ! Pesticules Section 61 Forsym St. SAV Athon. GA 300001 Phone: 104,562 8987 Januil: Tomezak,kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 2:58 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

Zoetis has a site in Kalamazoo MI that I have been told is an EPA registered site. I will find out the details and send them to you.

# Regards,

Chris Sebley I Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

<image001.gif>

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, July 12, 2018 2:10 PM

**To:** Sebley, Christopher H **Cc:** Doireann O'Brien

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source

Hi Christopher,

If we were to allow you to relabel the product, where would the relabeling take place? The product would need to be relabeled in a EPA Registered Establishment.

# Thank you,

Kuntarly Toniczak, Life Science:
US Environmental Protection Agency, Region 3
Posticules Section
64 Fosciti St. SAV Atlanta, GA 30303
Phone: 10 (L02,898)
tunal: Tomczak, kimberly@cpa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

**Subject:** Re: Entry # U16-10064192

Kimberly,

We would get enough labels from the manufacturer that match the master label you have on file. They have revised the label recently to ensure they match.

Regards, Chris Sebley

Sent from my iPhone

On Jul 11, 2018, at 8:38 AM, Tomczak, Kimberly <Tomczak.Kimberly@epa.gov> wrote:

MOTICE: This message originates from an external source.

Hi Chris,

If we allowed you to relabel this product, would you relabel using the last EPA registered label?

Or were you looking to make a notification/amendment change to revise the label?

# Thank you,

Kuntierty Tennezal. Life Scients:
L'S Lingueung utal Protection Agency. Region 1
Pesneules Section
of Forsch St. SW Arbana (LA 3030.3)
Phone: 104.562.8987
Cinatic Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

Subject: Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly <Tomczak, Kimberly@epa.gov> wrote:

NOTICE: This message originates from an external source.

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kimport Concak, UK Scientst
US Pavirouncual Protection Agency Region 1
Periodics Section
of Corseth Sc SM Atlanta, CA 2006a;
Phone: 104.562.8987
Linear Tomezak, kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL

**TABLETS** 

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

- 1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.
- 2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

### Regards,

Chris Sebiey | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham,

NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 |

christopher.sebley@zoetis.com Visit Us: zoetis.com/poultry

#### <image001.gif>

# Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Thursday, July 19, 2018 9:26 AM

To:

Tomczak, Kimberly

Subject:

FW: Entry # U16-10064192

importance:

High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

Regards,

Chris Sebley | Senior Manager | Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Sebley, Christopher H

**Sent:** Tuesday, July 17, 2018 3:11 PM **To:** Tomczak.kimberly@epa.gov

Cc: Bucher, Art

Subject: FW: Entry # U16-10064192

Importance: High

Kimberly,

I was checking the EPA registry and found that the site currently storing the product in question is EPA registered. Is this sufficient to complete the re-labelling here?

Regards,

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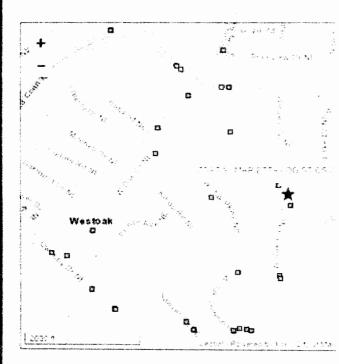
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# FOR ANIMALS. FOR HEALTH, FOR YOU.

### ZOETIS- MARIETTA LOGISTICS CENTER

EPA Registry Id: 110070021744 1950 WEST OAK CIRCLE MARIETTA, GA 30062



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# Legend

- Selected Facility
- B EPA Facility of Interest
- State/Tribe **Facility of Interest**

The facility locations idisplayed come from the FRS Special Coordinates tables. They are the best representative locations for the displayed facilities based on the accuracy of the collection method and quality assurance checks performed against each location. The Worth American flaturm of 1990, is used to display so coordinates.

# **Environmental Interests**

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		Facility Codes and flags		
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fic Contacts returned

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Sent: Tuesday, July 17, 2018 8:49 AM

To: 'Tomczak, Kimberly'

Subject: RE: Entry # U16-10064192

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I have located a company that will re-label the product in the Atlanta area.

PCA –Atlanta 6300 Boat Rock Blvd Suite E Atlanta, GA 30336

It is 24 miles from the current warehouse in Marietta GA (Zoetis Marietta Logistics Center, 1950 West Oak Circle, Marietta, GA) where the product is located. They will apply to become an EPA registered site to perform this work.

Please let me know as soon as you can if this acceptable. If not I need to start the export process as Customs has a dead line of 7/28/18 for this material to leave the country.

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Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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FOR ANIMALS. FOR HEALTH, FOR YOU.

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**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:12 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

Unfortunately, the product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

# Regards,

Kimberty Loniczaf, Lele Scientsi US Environmental Process in Agency, Region 1 Pesticides Sertion 51 Forsyth St. SW Atlantia, CA (3030) Phone (0.1.562.89s.) Email: Tomczak,kimberbarepa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

# Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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Kumberty Tomezak, Life Scientist US Environmental Protection Agency, Region ! Pesticides Section 6) Forsydr St. SW Adanta, GA 30308 Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

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Sent: Thursday, July 12, 2018 2:58 PM

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# Regards,

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Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

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**Subject:** RE: Entry # U16-10064192

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Knuberh Tours rate I she becount

US Lawronmental Protection Agency, Region 3 Pesticides Section 6) Forseth Nr. SAV Adama, GA 30303 Phone: 104,562,8987 Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

Subject: Re: Entry # U16-10064192

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Sent: Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

**Subject:** Re: Entry # U16-10064192

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Regards, Chris Sebley

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MBL # HLCUDUB180400955
CARTONS: 15 PALLETS / 1200 CASES – ANTI BACTERIAL TABLETS
ORIGIN – DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

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Please let us know how to proceed.

Regards,

Chris Sebley | Senior Manager Frocurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA Office: 919.314.2656 | Mobile: 919.896 4633 | <a href="mailto:christopher.sebley@zoetis.com">christopher.sebley@zoetis.com</a> Visit Us: <a href="mailto:zoetis.com/poultry">zoetis.com/poultry</a>

<image001.gif>

# Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Tuesday, July 24, 2018 4:36 PM

To:

Tomczak, Kimberly

Subject:

RE: Entry # U16-10064192

Kimberly,

That is good news on the extension.

I have asked the questions below to the supplier, Medentech, in Ireland and will let you know their response.

# Regards,

Chris Sebley | Senior Manager | Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

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Please consider the environment before printing this email! Thank you.

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, July 24, 2018 3:51 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

## Hi Christopher,

The Port of Charleston said they could extend the date.

Who is the importer for this shipment? If the company is foreign based, is there a facility in the United States that represents the company? Where is the based at?

# Regards,

Emberty Conceak, Lak Scientisi

US Environmental Protestion Agency, Region 4

Pesticide, Section

61 Forsuli M. SW Manta GARGOS

Phone: 10 L 562 898

Email: Teoriceak.kumberly depaster

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 19, 2018 9:26 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Subject: FW: Entry # U16-10064192

Importance: High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

# Regards,

Chris Sebley | Senior Manager, Procurement

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**Sent:** Tuesday, July 17, 2018 3:11 PM

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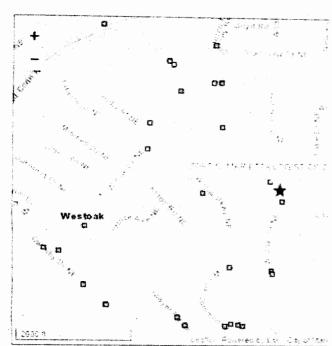


FOR ANIMALS, FOR HEALTH, FOR YOU.

& FRS FOCKING QUERY REQUEST & SPS FREEZ COLD Sec. X C WHAT COLONY IS TOWNERS &

# **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id: 110070021744 1950 WEST OAK CIRCLE MARIETTA, GA 30062



Facility Resistor Service (LRS) Civerview

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- ERSTEDBURGET DE TERET.
- EBS Liverica Defectiones
- FPs Tiessperior Modern

### Legend

- Selected Facility
- D EPA Facility of Interest
- □ State/Tribe **Facility of Interest**

The facility locations displayed come from the FRS Spatial Coordinates tables. They are the cest representative locations for the displayed facilities based on the accuracy of the collection method and quality assurance check performed spanish each location. The North American Casum of 1980 is used to display as as operanised.

# **Environmental Interests**

Information System	Section Facility Name	ht/Report Link	Inversemental	Source	Lass Updated Date	Supplemental Environmental Env
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#### Standard Industrial Classification Codes (SIC)

Daily Sprice	34 Code	ENERGY SPECIFICAL
NFDES	4225	GENERAL WAREHOUSENS AND STOPAGE

Description)

Frimary

# Facility Codes and Flags

EPA Region

National Industry Classification System Codes (NAICS)

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Congressional District Number

Legislative District Number

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tio Contacts returned

From: Sebley, Christopher H

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Kimberly Tone zak, Jafe Seignist.

US Environmental Protection Agency, Region 1

Pestindes Section

61 Forseth St. SM. Adams, GA 30303

Phone: 104, 762,8987

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Kimberly Toniczak, Life Scienisi

US Environmental Protection (Agency, Region 1)
Pesticides Section
61 Forsyth St. SW. Admin. 4-A, 30306
Phone: 404.562.8763
Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

**Sent:** Wednesday, July 11, 2018 8:45 AM

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Thank you,

Kunberly Lomezak Lab Scientist US Lavin anneal Protection Agency, Region 1 Peshedes Section 61 Forwith St. SM, Attang. GA 3030.3 Phone: 101./by/8987 Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

To: Tomczak, Kimberly <<u>Tomczak.Kimberly@epa.gov</u>>
Cc: Doireann O'Brien <<u>dobrien@medentech.com</u>>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL TABLETS

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been

placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.

2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

## Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA Office: 919.314.2656 | Mobile: 919.896 4633 | <a href="mailto:christopher.sebley@zoetis.com">christopher.sebley@zoetis.com</a>

Visit Us: zoetis.com/poultry

## <image001.gif>

# Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Wednesday, July 25, 2018 8:46 AM

To:

Tomczak, Kimberly

Cc:

'nroche@medentech.com'

Subject:

RE: Entry # U16-10064192

Kimberly,

The importer of Record is Medentech Limited in Ireland. Address is Whitemill Industrial Estate, Wexford, Ireland.

Medentech responded to your other request this morning with "We certainly have an authorised agent who acts for us in the US and our company has a registered address. However, we do not have a facility with an establishment number in the US which could be used for re-packing."

Please let me know how you would like to proceed with this shipment.

Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, July 24, 2018 3:51 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Christopher,

The Port of Charleston said they could extend the date.

Who is the importer for this shipment? If the company is foreign based, is there a facility in the United States that represents the company? Where is the based at?

# Regards,

Kumberty Tennezak Life Searmiss US Environmental Protection Agency, Remone) Pesticules Section 61 Forsyth St. SW Atlanta, CAN 207303 Phone: 104.562.8987 Limil: Tomezak, kindecily (contgo)

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 19, 2018 9:26 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

Regards,

Chris Sebley | Seriior Manager, Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

# FOR ANIMALS, FOR HEALTH, FOR YOU,

Please consider the environment before printing this email! Thank you.

From: Sebley, Christopher H

**Sent:** Tuesday, July 17, 2018 3:11 PM **To:** Tomczak.kimberly@epa.gov

Cc: Bucher, Art

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

I was checking the EPA registry and found that the site currently storing the product in question is EPA registered. Is this sufficient to complete the re-labelling here?

Regards,

Chris Sebley | Senior Manager, Producement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry



FOR ANIMALS, FOR HEALTH, FOR YOU.

# **ZOETIS- MARIETTA LOGISTICS CENTER**

1950 WEST OAK CIRCLE

MARIETTA, GA 30062

EPA Registry ld: 110070021744

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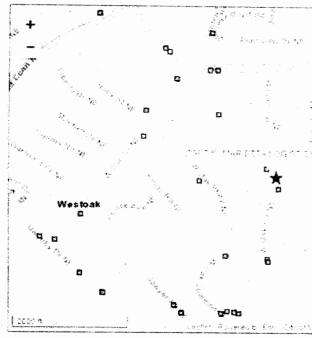
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# Legend

- Selected Facility
- D EPA Facility of Interest
- □ State/Tribe **Facility of Interest**

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#### **Environmental Interests**

Information System	- Sentom Excitity Name	Milkennetten System	Interest Type	Date	Last Updated Date	Supplemental Environmental Env
WARREST BOOK THAT COURT FOR FOR PARTIES ON	ZOETIS- MARIETTA LOGISTICS CENTER	GARADIS:	STORM WATER INDUSTRIAL	1015		
	COETIS MARIETTA LOGISTICS CENTRE	Special VI	1016-11/2065 17/01/- 11430/2	1016		

Additional EPA Reports Melines amount Enforcement and Compliance this Demographic . Est hity Court maket Vicenee Economicands limited May Vicenee Water the Arguet

# Standard Industrial Classification Codes (SIC)

Data Source	SK: Code	Personation	Property
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IPA Region	(hiệ	National Industry Classification System Codes (N	(AICS)
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Legislative Charter Number Facility Mailing Addresses HUC Code/Waterstard DS130001 LPPER CHATTAMOCCHEE

Us Meason Bossler Indicates tic Facility Maring Accresses returned Lederal Facility

Atternative Names tic Contacts returned From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 8:49 AM

To: 'Tomczak, Kimberly'

Subject: RE: Entry # U16-10064192

Kimberly,

I have located a company that will re-label the product in the Atlanta area.

PCA –Atlanta 6300 Boat Rock Blvd Suite E Atlanta, GA 30336

It is 24 miles from the current warehouse in Marietta GA (Zoetis Marietta Logistics Center, 1950 West Oak Circle, Marietta, GA) where the product is located. They will apply to become an EPA registered site to perform this work.

Please let me know as soon as you can if this acceptable. If not I need to start the export process as Customs has a dead line of 7/28/18 for this material to leave the country.

## Regards,

Chris Sebley I Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:12 PM

**To:** Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE. This message originates from an external source.

Hi Chris,

Unfortunately, the product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

# Regards,

Kunherly Tomezak, Life Scientist
US Environmental Protection Asyncy, Region 4
Pesticides Section
61 Forsyth St. SAV Adams, G.Y 30363
Phone: 10 Lo62.8987
Email: Tomezak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

# Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:00 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source

### Good afternoon,

The product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

# Regards,

Kumberly Temesak, tille Scientis I S Environmental Protection Agency, Region 5 Pesnedes Section Of Forsyth St. SW. Atlanta, GA (1990)

Phone: 104, 562,8987

Limili Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 2:58 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

**Subject:** RE: Entry # U16-10064192

Kimberly,

Zoetis has a site in Kalamazoo MI that I have been told is an EPA registered site. I will find out the details and send them to you.

# Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, July 12, 2018 2:10 PM

**To:** Sebley, Christopher H **Cc:** Doireann O'Brien

Subject: RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

# Hi Christopher,

If we were to allow you to relabel the product, where would the relabeling take place? The product would need to be relabeled in a EPA Registered Establishment.

### Thank you,

Kimberly Lomezak Tale Scientis:

US Environmental Protection Agency, Region 3

Pesticules Section.

of Forsyth St. SW Adamba, C.A. Millott.

Phone: 104,562,8257

Lineal: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

**Sent:** Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

Subject: Re: Entry # U16-10064192

Kimberly,

We would get enough labels from the manufacturer that match the master label you have on file. They have revised the label recently to ensure they match.

Regards, Chris Sebley

Sent from my iPhone

On Jul 11, 2018, at 8:38 AM, Tomczak, Kimberly < Tomczak.Kimberly@epa.gov> wrote:

NOTICE: This message originates from an external source.

Hi Chris,

If we allowed you to relabel this product, would you relabel using the last EPA registered label?

Or were you looking to make a notification/amendment change to revise the label?

Thank you,

Kimberly Lonezak, Life Scienus US Environmental Protection Agency, Region 1 Pesticules Section 61 Forsyth St. SW Adama, GA 30503 Phone: 104.562.8987

Final: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

**Sent:** Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

**Subject:** Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly < Tomczak. Kimberly@epa.gov > wrote:

NOTICE: This message originates from an external source

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kimberty Loniczak, Life Scientist US Lawronnie nial Protection Agency, Region 1 Pesticides Section of Fersyll, St. SW. Atlanta, GAV, 303003 Parone: 104,562,8987 Ennalt: Tomczak, kimberty@cpa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955 CARTONS: 15 PALLETS / 1200 CASES – ANTI BACTERIAL TABLETS ORIGIN – DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been

placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.

2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

## Regards,

Chris Sebley | Senio: Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA Office: 919.314.2656 | Mobile: 919.896 4633 | <a href="mailto:christopher.sebley@zoetis.com">christopher.sebley@zoetis.com</a> Visit Us: <a href="mailto:zoetis.com/poultry">zoetis.com/poultry</a>

## <image001.gif>

# Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Wednesday, July 25, 2018 4:26 PM

To:

Tomczak, Kimberly

Subject:

RE: Entry # U16-10064192

Kimberly,

This is good news that we can re-label in the USA.

We would like to use the Zoetis Marietta Logistics Center EPA Registry ID: 110070021744. Details below. The product is also located here and is "on-hold".

Regards,

Chris Sebley i Senior Manager. Propinement

Zoetis : Global Biodevices and Automation: 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

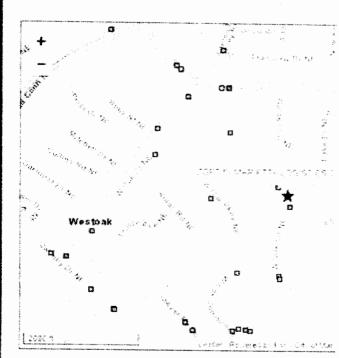
zoetis

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FRS Facility Query Result X

# **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id: 110070021744 1950 WEST OAK CIRCLE MARIETTA, GA 20062



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on System Codes (MAICS)

# Legend

- \* Selected Facility
- D EPA Facility of Interest
- □ State/Tribe
- Facility of Interest

The facility locations displayed come from the FRS Scattal Coordinates tables. They are the cest representative locations for the displayed facilities based on the accuracy of the polection method and quarty assurance checks performed against each peaches. The North American Datum of 1980 is used to display, all operations.

#### **Environmental Interests**

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Additional EPA Reports MyEnenaments: Enforcement and Compliance late Genous aphins: Endity Contributes Surveyer: Engrowmental Justice Way Viewer: Watershed Reports

#### Standard Industrial Classification Codes (SIC)

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typoes	4235	GENERAL WAREHOUSING AND STORAGE	

#### Facility Codes and Stags

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ative Names for Contacts returned

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, July 25, 2018 1:02 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an extense source

Hi Chris.

We will allow you to relabel the product under a Stop, Sale Order. Can you provide me with the name and establishment number for the facility you plan to relabel at?

Once the Order is issued, you will be allowed to move and relabel the product. At this time, the product is to remain where it is currently located.

Thank you,

Knoberk Tomezak, Life Seichtst. US Environmental Protection Agency, Region 3 Pesticules Section 61 Forsuli St. SW Adamia, CA 30303 Phone: 104,562,8987

Email: Fornezak kiniberty & coargos

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Tuesday, July 24, 2018 4:36 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

That is good news on the extension.

I have asked the questions below to the supplier, Medentech, in Ireland and will let you know their response.

Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry



FOR ANIMALS, FOR HEALTH, FOR YOU.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, July 24, 2018 3:51 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Christopher,

The Port of Charleston said they could extend the date.

Who is the importer for this shipment? If the company is foreign based, is there a facility in the United States that represents the company? Where is the based at?

### Regards,

Kumberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section; 61 Forsyth St. SW. Atlanta, GA 30305 Phone: 104 552,8987 Limit, Tomezak, kurbetly (contage)

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 19, 2018 9:26 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

## Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry



FOR ANIMALS, FOR HEALTH, FOR YOU.

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 3:11 PM

To: Tomczak.kimberly@epa.gov

Cc: Bucher, Art

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

I was checking the EPA registry and found that the site currently storing the product in question is EPA registered. Is this sufficient to complete the re-labelling here?

# Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher sebley@zoetis.com

Visit Us: zoetis.com/poultry

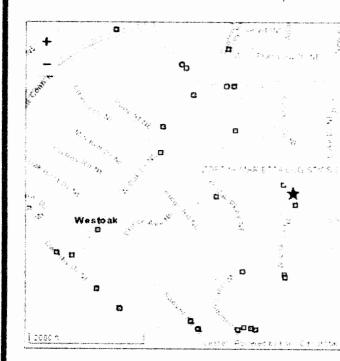


FOR ANIMALS. FOR HEALTH, FOR YOU.

#### **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id: 110070021744

1950 WEST OAK CIRCLE MARIETTA, GA 30062



## Legend

- \* Selected Facility
- EPA Facility of Interest
- □ State/Tribe **Facility of Interest**

The facility locations displayed come from the FRS Special Coordinates tables. They are the best representative bloodsons for the displayed facilities based on the stopiacy of the colection method and quality, assurance checks performed against each location. The forth American Chaum of 1980 in used to display as opposing the coordinates.

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#### **Environmental Interests**

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#### Standard Industrial Classification Codes (SIC)

Description.

SIC Coste

Data Source

MPOE3	43%2	GEMERAL WAPEHOUSING AND STORAGE	
		Facility Codes and Flags	
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#### Regards,

Kumberly Lonnezuk, Cak Sciennisi US Luvhoramental Protection, Aseney, Region -Pesticides Sciencia UT Corsysh St. SAV Adama, GA 30303 Phone: 104.562,8987

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Limil: Tomczak.kimberly@epa.gov

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

#### Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

## zoetis

FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:00 PM

To: Sebley, Christopher H

Subject: RE: Entry # U16-10064192

NOTICE: This message uniquates from an external source.

#### Good afternoon,

The product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

#### Regards,

Kunberk Tomezak, Tafe Sciepps CS Environmental Protection Agency, Region of Pesticides Section of Porsych SCSW, Adams, CAN 00305 Phone: 404, 662,8087

.

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 2:58 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Final Tomczak.kimberly@epa.gov

Kimberly,

Zoetis has a site in Kalamazoo MI that I have been told is an EPA registered site. I will find out the details and send them to you.

#### Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, July 12, 2018 2:10 PM

**To:** Sebley, Christopher H **Cc:** Doireann O'Brien

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Hi Christopher,

If we were to allow you to relabel the product, where would the relabeling take place? The product would need to be relabeled in a EPA Registered Establishment.

Thank you,

Kimberty Foraczak, Life Scientist

US Environmental Protection Agency, Region 1

Pesticides Section

of Forsyll St. SW Allama, GA 300001

Mana. 191.362.8983

Famil: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

Subject: Re: Entry # U16-10064192

Kimberly,

We would get enough labels from the manufacturer that match the master label you have on file. They have revised the label recently to ensure they match.

Regards, Chris Sebley

Sent from my iPhone

On Jul 11, 2018, at 8:38 AM, Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > wrote:

NOTICE. This message originales from an external source.

Hi Chris,

If we allowed you to relabel this product, would you relabel using the last EPA registered label?

Or were you looking to make a notification/amendment change to revise the label?

Thank you,

Kimberly Tounczak, Lab. Scientist US Fuvironmental Protection Agency, Region 4 Pesticides Section 64 Forsyth St. SM Arkanta, CA 30303 Phone: 404,562,8987

Family Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

**Subject:** Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > wrote:

NOTICE: This message originates from an external source.

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kimberly Lomezak, Life Scientist US Loviconmental Provenieri Agency, Region 3 Pesticules Section of Vests the Section Phone: 104,562,8787 Cruaik Tomezak, kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL TABLETS

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been

placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.

2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

Regards,

Chris Sebley ; Semor Manager, Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA Office: 919.314.2656 | Mobile: 919.896 4633 | <a href="mailto:christopher.sebley@zoetis.com">christopher.sebley@zoetis.com</a> Visit Us: zoetis.com/poultry

<image001.gif>

## Tomczak, Kimberly

From:

Jim Fazal <jfazal@americancargoexpress.com>

Sent:

Wednesday, August 08, 2018 5:07 PM

To:

Tomczak, Kimberly; 'AHANLEY@MEDENTECH.COM'; Miguel Rivera

Cc:

Bauman, Michael, Ho, Kanoelehua; Jim Fazal

**Subject:** 

RE: Entry Number U16-10084042

Officer Tomczak,

Here is the information you requested....

Label 2-20-609H is the tub label only.

Label 2-20-766D is the outer carton label only.

Container is at the terminal in Charleston SC waiting for custom release....

Hope this help!

From: Jim Fazal

Sent: Wednesday, August 08, 2018 4:53 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' <AHANLEY@MEDENTECH.COM>;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Jim Fazal

<jfazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Hello,

The information below has been requested from the importer.... As per our conversation please see additional information attached....

I will have an answer for you first thing tomorrow am...

Thank you so much for your help!

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Wednesday, August 08, 2018 4:41 PM

To: Jim Fazal < ifazal@americancargoexpress.com >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera <a href="mailto:mrivera@AmericanCargoExpress.com">mrivera@AmericanCargoExpress.com</a>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Hi Jim,

Where is this product currently located? In addition, the label you uploaded includes two labels, a full label and a front label. Are both labels affixed to the outside of the container?

#### Thank you for your patience with this entry.

#### Regards,

Kimberly Toniczak, Life Scienise US Environmental Protection Agency, Region J Pesticines Scenon, Of Lorsyth St. SW. Adama, GA 3030.1 Phone: 404.562.8087 Limil: Toniczak.kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

**Sent:** Tuesday, August 07, 2018 5:26 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera <a href="mailto:mrivera@AmericanCargoExpress.com">mrivera@AmericanCargoExpress.com</a>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Jim Fazal

<jfazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Hello,

As per your request the entry has been update and the net weight in the PDA Data should match now.... Thank you!

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Sent: Tuesday, August 07, 2018 4:50 PM

To: Jim Fazal < ifazal@americancargoexpress.com>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM'>;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Hi Jim,

The entry now contains the correct labels. Thank you for uploading them.

The net weight in the PGA Data is incorrect. The net weight on the product label is different from the net weight in the PGA Data.

Please let me know once the entry has been revised.

#### Regards,

Kimberly Tomerak, Late Sciencist US Fragmentinental Protection Agency, Region & Pesticides Section 64 Forsyth St. SAV Athania, GA 30303 Phone: 104,562,8987 Email: Tomezak,kimberly@epa.gov From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Tuesday, August 07, 2018 2:38 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10084042

Hello Officer Tomczak,

I was able to get better copies from the importer.... Hope this helps.... I also uploaded in DIS...

From: Jim Fazal

Sent: Tuesday, August 07, 2018 1:08 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>

Subject: RE: Entry Number U16-10084042

Good afternoon Officer,

I uploaded the labels in DIS again, it should be ok now.... Kindly advice if all in order?

Sorry for the trouble!

Thank you, Jim

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Tuesday, August 07, 2018 11:09 AM

To: Jim Fazal < ifazal@americancargoexpress.com >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Hi Jim,

The labels that were uploaded do not include the full label.

Please let me know once the full label is uploaded.

Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region I Pesticides Section of Forsyth St. SAV Adamta, GA 36363 Phone: 404,562,8987

Fmail: Tomczak.kimberly@cpa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Tuesday, August 07, 2018 9:39 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Jim Fazal

<ifazal@americancargoexpress.com>
Subject: RE: Entry Number U16-10084042

Good morning,

Labels were uploaded to DIS and successfully received.... Please see attached...

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Tuesday, August 07, 2018 9:20 AM

To: Jim Fazal < ifazal@americancargoexpress.com>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Good morning,

Copies of the labels that are affixed to the containers/cases will need to be uploaded to DIS in ACE.

Please upload the labels by COB today.

Thank you,

Kunberty Louis zak Aufe Sciencia US Environmental Protection Agency, Region 1 Pesticides Scritions G1 Forseth St. SW Atlanta, GA 363001 Phone: 404.562.8287 Finall: Tomczak.kimberty@epa.gov

**From:** Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Monday, August 06, 2018 4:33 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Jim Fazal

<ifazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Hello Officer Tomczak,

I am following up on my email below.... kindly advice if labels below are sufficient enough to release our shipment.

Thank you

Jim

Pls note labels were also uploaded in DIS....

From: Jim Fazal

Sent: Friday, August 03, 2018 4:58 PM

**To:** 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM'>; Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: 'Bauman, Michael' <bauman.michael@epa.gov>; 'Ho, Kanoelehua' <ho.kanoelehua@epa.gov>; Jim Fazal

<ifazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Good afternoon.

Below has been uploaded to DIS... hope it is sufficient...

# DIRECTIONS FOR USE It is a notation of Sederal law to use this product in a manner inconsistent with its labeling Read the entire label and use strictly in accordance with precautionary statements and cirretures. INOVOTABS\* is for certainse use in the Zodio Emizex Inovoyect at 2 tahlety per guilon water. DARY USE OF INDVOTABS. 1) Treated needle surfaces will be west during the sampzation phase of the invectionable. 2) It is not seen meed involvations solution for more than one processing day or when the solution between during the sampzation phase of the invectionary of the containers of the containers of the relation of the relational phase of the relationary of the labels. 3) The next set with insortations and cause other components to rest present on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the label. 3) Webenitich and locks make 46 other dams for use other than more listed on the labels. 4) Webenitich and locks make 46 other dams for use other than more listed on the labels. 5) Webenitich and locks make 46 other dams for use other for more listed on the labels. 6) Webenitich and locks make 46 other dams for use other for more listed on the labels. 7) Add 3 foromation specifies in 1 gallon of when water 1997-1041-1011 Add C. Lower temperature will exceed the sederal production of the labels. 8) Webenitich and the labels. 8) Webenitich and the labels of the labels of

STORAGE AND DISPOSAL

Denot contominate water, find or find by storage and disposal.

Pestificide Storage: State in a roof, dig, well-vertisited area, Do not store at temperatures above 194% (40°C).

Pestificide Storage: States in cooking from the use of the product may be disposed of consistering in a tolest, or senior and senior by a sonitary state or an approprie waste disposal final injury to pestificial.

Container Manadling: Necrosification controlled to the controlled Roots entry container throughly with water to dispose prior to disposal. Offer for recyfor, if a salability.



INOVOTABS\* is an effective sanitizer in areas where it is of primcontamination on the needles in the Embrex Inovoject. Inovotabs\* Staphylosoccus aureus (ATCC 6538) and Klebsfella pneumoni.

INOVOTABS is for excusive use with Embrex\* Inovoject.

**INOVOTABS** are a single step effervescent tablet that is dissolved water (1 tablet for every 2 quarts or 2 liters of water), inovotable more consistent pit and stable chlorine concentration over time. It allows this product to perform well in the presence of organic chain the commercial hatchery environment.

Each tablet will produce a minimum of 2221 ppm chlori in two quarts of water.

NET CONTENTS: 250 Tablets

Distributed by

zoetis

Zoetis Inc. 333 Portage Street Kalamazoo, Mi 49007 U.S.A. Phone USA:1-800-849-3372 International: +1 919-941-5185

2-20-609H

Manufactured by:
Medentech

Medentech LTD.,
Whitemill Ind. Estate,
Clonard Road,
Wexford, Iroland
Tel: +353.53.9117900
Fax: +353.53.9141221
www.medentech.com
BATCH NUMBER:

EXPIRATION DATE:

EPA 96G NO 73847 3 1507 EPA 681 NO 71847 (8) 1

# novota

Effervescent Sanitizer Tablets On in the Embrex® Inovoje

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Cons

Strain 191

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fax. 4

WWW

13/00/8

#### FIRST AID Hold was open and race slowly and gently with water for 15 - 20 minutes. Fernove contact lenses, if present, after the first 5 minutes, then continue rinking eye. Call a poison control centar or doctor for treatment advice. Move presento festi ex if masked If pursuits not preaching, call 91° or an ambulance, then give artificial impirations. professibly by exouth to mouth, if possible "Eath a possion control center or doctor for further treatment advice. Take off contaminated detiring or skin Recommission representations with planty of wrater for 15 - 20 minutes Call a poisson control certes or doctor for treatment advice it swallowed - • Call poison control center or doctor animadately for treatment advice How person up a glass of water if able to swallow. Do not induce varning unless told to do so by the payon control center or doctor. Do not give anything by mouth to an unconscious person. Have the product container or label with you when calling a powon central center of doctor. or going for treatment You may also contact 1.800.420.9236 for emergency medical treatment information NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gasting lawage CONTAINS: Anhydrous Sodium Dichloroisocyanurate NaCL(NCO), CAS NO 2893-78-9

From: Jim Fazal

Sent: Friday, August 03, 2018 3:15 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; AHANLEY@MEDENTECH.COM; Miguel Rivera

<mrivera@AmericanCargoExpress.com>

Subject: RE: Entry Number U16-10084042

Good afternoon Officer.

As per your request the net weight in PGA Data has ben updated and documents were uploaded to DIS.

Hope all is sufficient.

Thank you, Jim Fazal

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Friday, August 03, 2018 2:58 PM

To: AHANLEY@MEDENTECH.COM; Jim Fazal <ifazal@americancargoexpress.com>; Miguel Rivera

<mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: Entry Number U16-10084042

Good afternoon,

For entry number U16-10084042, please address the following point(s) within 72 hours for the review of the entry:

- Please upload a legible label to DIS;
- Incorrect net weight in PGA Data.

The status of the entry should remain "hold intact" until the above mentioned issues have been resolved or additional information is provided. If you have questions or would like additional information regarding this shipment, I may be contacted by phone or email (see below).

#### Regards,

Kimberly Fonezak, Life Scientsi US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, CA 30303 Phone: 404.562,8987

Email: Tomczak.kimberly@epa.gov

## Tomczak, Kimberly

From:

Nicola Roche <nroche@medentech.com>

Sent:

Tuesday, August 14, 2018 4:15 AM

To:

Tomczak, Kimberly; Sebley, Christopher H

Cc:

Bauman, Michael; Ho, Kanoelehua

Subject:

**RE: Zoetis** 

Good morning Kimberly,

Thank you for the report and your guidance, we will update all labels as per your request.

Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nroche@medentech.com M/ +353 86 805 9380 T/ +353 53 911 7929



HYPRED KIKO

antigerm medenbech 63

141 PO 25VE 493



www.kersir.group.com

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Monday 13 August 2018 19:58

To: Sebley, Christopher H <christopher.sebley@zoetis.com>; Nicola Roche <nroche@medentech.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>

Subject: Zoetis Importance: High

Good afternoon,

Attached you will find the Stop, Sale Order for the two imported Medentech shipments.

Please let me know if you have any questions.

Regards,

Kumberly Louiczak, Lite Scientist US Environmental Protection Agency, Region J Pesticides Section 61 Forsyth Sr. 533 Atlanta, CAV 30507 Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

## Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Friday, August 03, 2018 10:58 AM

To:

Tomczak, Kimberly

**Subject:** 

RE: Entry # U16-10064192

#### Kimberly,

Yes I have contacted Contrpac Inc., and they have provided a quote to me for the re-labelling work. I have explained the nature of the product and they are ok with performing this task.

I explained that we will need photographs and/ or an on-site visit from the EPA or their representative.

#### Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

#### FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Friday, August 03, 2018 10:53 AM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message orginates from an external source.

#### Hi Chris,

Is Contrapac, Inc. aware that you plan to relabel the product there and are they okay that you are taking it there?

#### Thank you,

Kimberty Tomezal, July Scientist US Environmental Protection Agency, Region a Pesticule's Section of Forsyth St. SAV Arlance, CeN 20303 Phone: 404,562,8983 Junaily Vonczak Kumberty y cpaczoy From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, August 03, 2018 8:54 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

This arrived at the Marietta, GA warehouse on 5/15 and was received into our inventory system on 5/29.

#### Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

#### FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Friday, August 03, 2018 7:08 AM

To: Sebley, Christopher H

Subject: RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Hi Chris,

What was the date the Inovotabs were transported to Zoetis's facility in Marietta, Georgia from the Port?

#### Thank you,

Kimberk Tourszak, Life Scienosi

US Environmental Protection Agency, Region 1

Pesticides Section

of Fersyll, St. SAV Adams, GA 200001

Phone: 104,562 8987

Email: Tona cak knoberty (cepager)

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, August 01, 2018 4:37 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

The label is on the case. The product arrived at the port of Charleston on April 27<sup>th</sup> 2018.

Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

#### FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 01, 2018 3:57 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source

Hi Chris,

Is the label on the case and the plastic tubs? Or just the case?

In addition, when did the product arrive at the port?

Thank you for the information.

Regards,

Kumberly Tomezak, Elle Scientist US Environmental Protection Agency, Region 3 Pesticites Section 61 Possyth St. SAV Arbanta, CA 30 363 Phone: 404,502,8987

Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, August 01, 2018 2:29 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

Each case weighs 23.2 lb. (10.5 kilograms). The case is cardboard and contains 2 plastic tubs.

#### Thanks,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

## zoetis

FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 01, 2018 12:58 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

What is the weight of the containers you are holding? Are they supersacks, containers or drums?

Just want to make sure I get the correct information in the Stop, Sale Order.

#### Thank you,

Kamberly Tomezak, Life Scientist US haveronmental Protection Agency, Region 4 Pesticines Section 61 Forseth St. SW Arbania, GA 30303 Phone: 404,562,8987 harail: Tomezak,kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 26, 2018 4:12 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Subject: RE: Entry # U16-10064192

Kimberly,

I have located a company in the Atlanta area with EPA Establishment #: 52270-GA-01 that I will use to relabel the product.

Contrapac Inc

Labeling Location: 675 Great Southwest Parkway, Atlanta, GA 30336

EPA Est. Number: 52270-GA-01

It is located 25 miles from the current location of the product in Marietta, GA.

Please let me know if this is acceptable?

Regards,

Chris Sebley | Senior Manager, Producement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry



FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, July 25, 2018 4:28 PM

**To:** Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source

Hi Chris,

Do you have the EPA Establishment Number for the facility? I'm not familiar with the EPA Registry ID.

Thank you,

Kunberly Tomezak, Life Scientisi US Finanonimental Protection Agency Region 1 Pesticides Section 61 Forsyth St. SW Adamb., GA 30303 Phone: 404.562.8987

Limil: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 25, 2018 4:26 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

**Subject:** RE: Entry # U16-10064192

Kimberly,

This is good news that we can re-label in the USA.

We would like to use the Zoetis Marietta Logistics Center EPA Registry ID: 110070021744. Details below. The product is also located here and is "on-hold".

#### Regards,

Chris Sebiey | Senior Manager, Procurement

Zoetis Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

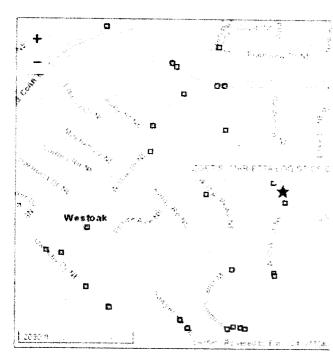
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#### **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id. 110070021744 1950 WEST OAK CIRCLE MARIETTA, GA 30062



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#### Legend

- \* Selected Facility
- D EPA Facility of Interest
- □ State/Tribe

**Facility of Interest** 

The facility locations displayed come from the FRS Spatial Coordinates tables. They are the best representative boat one for the displayed facilities based on the accuracy of the collection method and quality assurance checks performed against each location. The North American Catum of 1980 is used to display a coordinated.

#### **Environmental Interests**

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#### Standard Industrial Classification Codes (SIC)

Data Source	SK" Couse	Description .
NPDE5	4225	GENERAL WAREHOUSING AND STORAGE

GENERAL WAREHOUSING AND STORAGE

#### Facility Codes and Flags 34

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Company a grant of Physic	nucl Streamtons	9.2	

Permary

Legislative District National

HIK Code/Watershed

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Facility Mailing Addresses

US Mexica Boyder Inductor

Leiteral Facility

Fribat Land

FPA Region

No Facota Mailing Addresses returned

Contacts

National Industry Classification System Codes (MAICS)

Afternative Names

tic Contacts returned

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, July 25, 2018 1:02 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE. This message originates from an external source.

Hi Chris,

We will allow you to relabel the product under a Stop, Sale Order. Can you provide me with the name and establishment number for the facility you plan to relabel at?

Once the Order is issued, you will be allowed to move and relabel the product. At this time, the product is to remain where it is currently located.

Thank you,

Kimberly Tomczak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section of Forsyth St. SW. Atlanta, GA 20503 Phone: 104,562,8987 Email: Tomczak,kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

**Sent:** Tuesday, July 24, 2018 4:36 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

That is good news on the extension.

I have asked the questions below to the supplier, Medentech, in Ireland and will let you know their response.

Regards;

Chris Sebley | Senior Manager | Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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FOR ANIMALS, FOR HEALTH, FOR YOU

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, July 24, 2018 3:51 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Christopher,

The Port of Charleston said they could extend the date.

Who is the importer for this shipment? If the company is foreign based, is there a facility in the United States that represents the company? Where is the based at?

#### Regards,

Kimberty Louiszak, Life Scientisi US Environmental Protection Agency, Region 1 Pesticules Section (it Forsith St. SW. Athana, GA 3030) Phone: 404.552.8987 Limil: Tomczak, kimberty@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 19, 2018 9:26 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: FW: Entry # U16-10064192

Importance: High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

#### Regards,

Chris Sebley | Semor Manager, Procurament

Zoetis i Global Biodevices and Automation, 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry



FOR ANIMALS, FOR HEALTH, FOR YOU.

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 3:11 PM

To: Tomczak.kimberly@epa.gov

Cc: Bucher, Art

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

I was checking the EPA registry and found that the site currently storing the product in question is EPA registered. Is this sufficient to complete the re-labelling here?

## Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

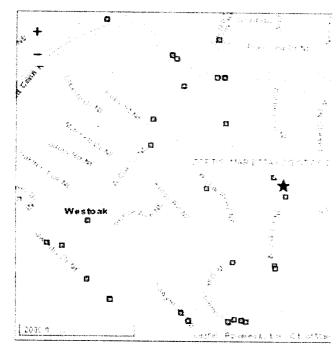
# zoetis

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**ZOETIS- MARIETTA LOGISTICS CENTER** EPA Registry Id: 110070021744

1950 WEST OAK CIRCLE MARIETTA, GA 30062



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#### Legend

- · Selected Facility
- EPA Facility of Interest
- D State/Tribe **Facility of Interest**

The faculty locations displayed came from the FRS Special Coordinates tables. They are the best respectables of the coat one far the displayed facilities based on the accuracy of the collection method and quality absurance sheeks performed against each location. The facility American Catum of 1933 is used to display a coordinates.

#### **Environmental Interests**

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,		Facility Codes and Flags		
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Lengeral Facility	₹ .			And Carried Ligar. A wind capacity land committee.

Atternative Names

Embas Cand

No Contacts returned

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 8:49 AM

To: 'Tomczak, Kimberly'

**Subject:** RE: Entry # U16-10064192

Kimberly,

I have located a company that will re-label the product in the Atlanta area.

PCA –Atlanta 6300 Boat Rock Blvd Suite E Atlanta, GA 30336

It is 24 miles from the current warehouse in Marietta GA (Zoetis Marietta Logistics Center, 1950 West Oak Circle, Marietta, GA) where the product is located. They will apply to become an EPA registered site to perform this work.

Please let me know as soon as you can if this acceptable. If not I need to start the export process as Customs has a dead line of 7/28/18 for this material to leave the country.

#### Regards,

Chris Sebley | Senior Manager, Procurement Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA Office: 919.314.2656 | Mobile: 919.896 4633 | <a href="mailto:christopher.sebley@zoetis.com">christopher.sebley@zoetis.com</a> Visit Us: zoetis.com/poultry

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Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, July 12, 2018 3:12 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

Unfortunately, the product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

#### Regards,

Knuberly Tone zak, Life Scientist US Invitopmental Protection Agency Region & Pesticides Section 04 Forsyth St. SAV Atlanta, GA 30303 Phone: 104,562,8987 Umail: Tonezak,kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

#### Regards,

Chris Sebley | Senior Manager Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

## zoetis

#### FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:00 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Good afternoon,

The product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

#### Regards,

Kumberly Joniczak, Jafe Scienisa US Engliconnental Protection Agency, Region 3 Pesticides Sections of Forsyth St. SM. Atlanta, GA 30303

Phone: 101.362.8987

Email: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 2:58 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

Zoetis has a site in Kalamazoo MI that I have been told is an EPA registered site. I will find out the details and send them to you.

#### Regards,

Chris Sebley | Senior Manager | Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

## zoetis

FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 2:10 PM

**To:** Sebley, Christopher H **Cc:** Doireann O'Brien

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Hi Christopher,

If we were to allow you to relabel the product, where would the relabeling take place? The product would need to be relabeled in a EPA Registered Establishment.

#### Thank you,

Kumberly Tomezak, Life Scientist

US Environmental Protection Agency, Region 4 Pesticides Section

of Forsyth Mr. SAV Admars Co.A. 10 30.5

Phan: 101. 64.8927

Linail: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > Cc: Doireann O'Brien < dobrien@medentech.com >

**Subject:** Re: Entry # U16-10064192

Kimberly,

We would get enough labels from the manufacturer that match the master label you have on file. They have revised the label recently to ensure they match.

Regards, Chris Sebley

Sent from my iPhone

On Jul 11, 2018, at 8:38 AM, Tomczak, Kimberly < Tomczak. Kimberly@epa.gov > wrote:

NOTICE This message originates from an external source.

Hi Chris,

If we allowed you to relabel this product, would you relabel using the last EPA registered label?

Or were you looking to make a notification/amendment change to revise the label?

Thank you,

Kumberty Comezak, Life Scientist US Environmental Protection: Agency, Region J Periodics Section 61 Porsyth St. SW, Atlanta, GA 30305 Phone: 104,562,8387

hanaii: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > Cc: Doireann O'Brien < dobrien@medentech.com >

Subject: Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > wrote:

NOTICE. This message originates from an external source.

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kunberly Lomeonk, Life Scientist
US Environmental Protection Agency, Region 4
Pesticules Section
64 Forsyth St. SW Atlanta, GA 30303
Phone: 104.562.8987
Finally Tomezak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Doireann O'Brien < <u>dobrien@medentech.com</u>>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL TABLETS

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been

placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.

2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

#### Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

#### <image001.gif>

120

## Tomczak, Kimberly

From:

Jim Fazal <jfazal@americancargoexpress.com>

Sent:

Wednesday, August 29, 2018 4:05 PM

To: Cc: Tomczak, Kimberly

Rosemary Lewis

Subject:

RE: Entry Number U16-10084042

As per your request this was moved to Contrapac warehouse for relabelling...

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Wednesday, August 29, 2018 3:56 PM

To: Jim Fazal < jfazal@americancargoexpress.com>

Cc: Rosemary Lewis <rlewis@AmericanCargoExpress.com>

Subject: RE: Entry Number U16-10084042

Good afternoon,

Is this the same shipment that is included in the Stop, Sale Order?

#### Regards,

Kimberly Toraczak, Life Scienisi US Lavironmental Protection Agency, Report Pesticries Section 61 Forsyth St. SAV Atlanta, (c.N 3030) Phone. 404.562.8987 Unanl: Toraczak, kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Wednesday, August 29, 2018 3:14 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov> **Cc:** Rosemary Lewis < rlewis@AmericanCargoExpress.com>

Subject: RE: Entry Number U16-10084042

Hello Officer Tomczak,

we received a call from custom that the shipment is custom released and release has also been posted in AMS...

please confirm and advice if ok to move container.....

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From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Friday, August 10, 2018 12:40 PM

To: nroche@medentech.com

Cc: Bauman, Michael <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Jim Fazal

Good afternoon,

It was nice speaking with you today.

Per our discussion, the label submitted for the Inovotabs does not correspond with the pesticide's most current EPA-approved pesticide master label. More specifically, under the Step by Step Inovotabs Mixing Directions, the label does not contain step number 11, "Twist close plastic bag and close lid firmly after withdrawing tablets from container." In addition, the outer carton label does not make reference to full tub label and adds the sentence "Contains: Anhydrous Sodium Dichloroisocyanurate...CAS NO. 2893-78-9." In addition, the inside label does not include the statement "You may also contact [1-800-420-9236] for emergency medical treatment information."

Please let me know if you have any additional questions.

#### Regards,

Kunberly Vomezak, Life Scienter
US Environmental Protection Agency, Region 1
Pesticides Section
61 Forsyth St. SAV Atlanta, GA 30202
Phone: 104.562.8987
Limail: Tomezak,kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Friday, August 10, 2018 12:08 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Jim Fazal

<jfazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Hello,

I have updated the importer (Nicole Roche) with the status of this shipment. She would like to contact you today to discuss.

Below is her contact information.

Thank you for all your help!

**Nicola ROCHE** 

nroche@medentech.com

#### Thank you,

#### Jim Fazal

## Special Accounts Customs Brokerage

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North American Headquarters New Jersey Operations 2345 Vauxhall Rd Union, NJ 07083 Tel: 908-351-3400 x 3072

Fax: 908-289-2490

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For Terms & Conditions please refer to: http://www.americancargoexpress.com/terms-and-conditions.html

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Friday, August 10, 2018 10:41 AM

To: Jim Fazal < ifazal@americancargoexpress.com >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM' >;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Subject: RE: Entry Number U16-10084042

Hi Jim,

Are you available to discuss this shipment today? If so, what number can I reach you at? Thank you,

Kimberly Tomezak, Life Scientst US Environmental Protection Agency, Region 3 Pesticides Section 61 Fersyth St. SW Atlanta, GA 303000 Phone: 404.562.8987 Email, Tomezak, kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Wednesday, August 08, 2018 5:07 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM'>; Miguel Rivera < mrivera@AmericanCargoExpress.com>

**Cc:** Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Jim Fazal < ifazal@americancargoexpress.com >

Subject: RE: Entry Number U16-10084042

Officer Tomczak,

Here is the information you requested....

Label 2-20-609H is the tub label only. Label 2-20-766D is the outer carton label only.

Container is at the terminal in Charleston SC waiting for custom release....

Hope this help!

From: Jim Fazal

Sent: Wednesday, August 08, 2018 4:53 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Jim Fazal

<ifazal@americancargoexpress.com>
Subject: RE: Entry Number U16-10084042

Hello,

The information below has been requested from the importer.... As per our conversation please see additional information attached....

I will have an answer for you first thing tomorrow am...

Thank you so much for your help!

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Wednesday, August 08, 2018 4:41 PM

To: Jim Fazal <ifazal@americancargoexpress.com>; 'AHANLEY@MEDENTECH.COM' <AHANLEY@MEDENTECH.COM'>;

Miguel Rivera < mrivera@AmericanCargoExpress.com >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10084042

Hi Jim,

Where is this product currently located? In addition, the label you uploaded includes two labels, a full label and a front label. Are both labels affixed to the outside of the container?

Thank you for your patience with this entry.

Regards,

Kimberly Fornezak, Cale Scienns!
US Environmental Propertion Agency, Region 1
Pesticides Section
of Forsytte St. SW Attanta. C. V. (1930)
Phone: 10 L.502.8987
Email: Tomezak.kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Tuesday, August 07, 2018 5:26 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' <AHANLEY@MEDENTECH.COM>;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Jim Fazal

<jfazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Hello,

As per your request the entry has been update and the net weight in the PDA Data should match now.... Thank you!

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Tuesday, August 07, 2018 4:50 PM

To: Jim Fazal < ifazal@americancargoexpress.com >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Hi Jim,

The entry now contains the correct labels. Thank you for uploading them.

The net weight in the PGA Data is incorrect. The net weight on the product label is different from the net weight in the PGA Data.

Please let me know once the entry has been revised.

#### Regards,

Kumberly Tornezak, Life Scienist 1-8 Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyin St. SW Adams, CA 30303 Phone: 104,562,8983 Limat: Tomezak,kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Tuesday, August 07, 2018 2:38 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>>; Ho, Kanoelehua < <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>> Subject: RE: Entry Number U16-10084042

Hello Officer Tomczak,

I was able to get better copies from the importer.... Hope this helps.... I also uploaded in DIS...

From: Jim Fazal

**Sent:** Tuesday, August 07, 2018 1:08 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>

Subject: RE: Entry Number U16-10084042

Good afternoon Officer,

I uploaded the labels in DIS again, it should be ok now.... Kindly advice if all in order?

Sorry for the trouble!

Thank you, Jim

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Tuesday, August 07, 2018 11:09 AM

To: Jim Fazal < ifazal@americancargoexpress.com >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera <mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Hi Jim,

The labels that were uploaded do not include the full label.

Please let me know once the full label is uploaded.

Thank you,

Kimbeth Fomezak, Life Scienist US Environmental Protection Agency, Region 1 Pesticides Scittori 6) Forsyth St. SW Adams, GA 30303 Phone: (0 tab2.8987 timail: Tomezak,kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]
Sent: Tuesday, August 07, 2018 9:39 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Jim Fazal

<ifazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Good morning,

Labels were uploaded to DIS and successfully received.... Please see attached...

From: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Sent: Tuesday, August 07, 2018 9:20 AM

To: Jim Fazal < ifazal@americancargoexpress.com >; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM >;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Entry Number U16-10084042

Good morning,

Copies of the labels that are affixed to the containers/cases will need to be uploaded to DIS in ACE.

Please upload the labels by COB today.

Thank you,

Kamberk Toniczak, Life Sciencis: US Environmental Protection Agency, Region 3 Pesucides Section 61 Forsyli St. SW Adapta, GA 3050.5

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Jim Fazal [mailto:jfazal@americancargoexpress.com]

Sent: Monday, August 06, 2018 4:33 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM>;

Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <br/>
bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Jim Fazal

<jfazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Hello Officer Tomczak,

I am following up on my email below.... kindly advice if labels below are sufficient enough to release our shipment.

Thank you

Jim

Pls note labels were also uploaded in DIS....

From: Jim Fazal

Sent: Friday, August 03, 2018 4:58 PM

**To:** 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; 'AHANLEY@MEDENTECH.COM' < AHANLEY@MEDENTECH.COM'>; Miguel Rivera < mrivera@AmericanCargoExpress.com>

Cc: 'Bauman, Michael' <bauman.michael@epa.gov>; 'Ho, Kanoelehua' <ho.kanoelehua@epa.gov>; Jim Fazal

<jfazal@americancargoexpress.com>

Subject: RE: Entry Number U16-10084042

Good afternoon,

Below has been uploaded to DIS... hope it is sufficient...

# DIRECTIONS FOR USE It is a violation of Reporal Law to use this product in a manner inconsistent with its labeling was defined to entire lake and one strictly in accordance with precautionary statements and directures. INOVOTABS\* is for enthalive use in the Zoolis Embras Inovince of 2 tablets per gation waster. DARY USE OF BIOLOGIABS. It rested needs surfaces will be well during the sample processing pay of when the solution becomes disturbed to gated interest interest interest interest interest programs and interest on the service of the restriction of t



INOVOTABS\* is an effective saritizer in areas where it is of primcontamination on the needles in the Embrex Inovoject. Inovotabs\* Staphylococcus aureus (ATCC 6538) and Klebsfella pneumoni.

INOVOTABS is for excusive use with Embrex\* Inovoject.

INOVOTABS are a single step effervescent tablet that is dissolved water (1 tablet for every 2 quarts or 2 liters of water), inovotabs\* more consistent pH and stable chlorine concentration over time. It allows this product to perform well in the presence of organic chain the commercial hatchery environment.

Active Ingredient:

Inert Ingredients:

Total:

Each tablet will produce a minimum of 2221 ppm chlori in two quarts of water.

NET CONTENTS: 250 Tablets

Distributed by:

zoetis

Zoetis Inc.
333 Portage Street
Kalamazoo, MI 49007
U.S.A.
Phone USA:1-800-849-3372
International: +1 919-941-5185

2-20-6**09**H

Manufactured by:

Medentech
Medentech LTD.,
Medentech LTD.,
Medentech LTD.,
Wexford, Ireland
Tel: +353.53.9117900
Fax: +353.53.9141271
www.medentech.com
BATCH NUMBER:

BATCH NUMBER: K-

EPA HEG NO 71847 3 1007 EPA HST NO 71841 (RE 1

# novota

Effervescent Sanitizer Tablets On in the Embrex® Inovoje

and What are server	FIRST AID
Maringes	<ul> <li>Hold eye open and times slowly and gently with water for 15 - 20 minutes.</li> <li>Remove contact lances, if present, after the first 5 minutes, then continue rinuing eye.</li> <li>Cell a polition control center or doctor for treatment advice.</li> </ul>
t mhaled	<ul> <li>More person to fresh as.</li> <li>If person is not breathing, call 91 for an embulence, then give estificial respiration, preferably by mouth to mouth, if possible.</li> <li>Call a power control center or doctor for further treatment advice.</li> </ul>
fon skin or clothing	Take off contaminated clothing     Rends skin immediately with plenty of water for 15 - 20 minutes     Cell a poison control center or doctor for treatment advice
T malewed	<ul> <li>Cult porson control center or doctor immediately for treatment advice.</li> <li>Have person tip a glass of water if able to swallow.</li> <li>Do not induce condting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
·	ecclied container or label with you when calling a person control center or doctor, or going for treatment itsu contact 1-800-420-9236 for emergency medical treatment information.

13/21/8

From: Jim Fazal

Sent: Friday, August 03, 2018 3:15 PM

To: Tomczak, Kimberly < Tomczak, Kimberly@epa.gov>; AHANLEY@MEDENTECH.COM; Miguel Rivera

<mri>mrivera@AmericanCargoExpress.com></mr

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Entry Number U16-10084042

Good afternoon Officer,

As per your request the net weight in PGA Data has ben updated and documents were uploaded to DIS.

Hope all is sufficient.

Thank you, Jim Fazal

From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Friday, August 03, 2018 2:58 PM

To: AHANLEY@MEDENTECH.COM; Jim Fazal < ifazal@americancargoexpress.com >; Miguel Rivera

<mrivera@AmericanCargoExpress.com>

Cc: Bauman, Michael <br/>
<br/>
| Sauman, Michael | Sauman, Michae

Subject: Entry Number U16-10084042

Good afternoon,

For entry number U16-10084042, please address the following point(s) within 72 hours for the review of the entry:

- Please upload a legible label to DIS;
- Incorrect net weight in PGA Data.

The status of the entry should remain "hold intact" until the above mentioned issues have been resolved or additional information is provided. If you have questions or would like additional information regarding this shipment, I may be contacted by phone or email (see below).

#### Regards,

Kniberly Topiczak, Life Scientisi US Environmental Protection Agency, Region 1 Pesticides Section of Porsyth St. SW. Adams, GAN 30504 Phone: 404-562-8987

Email: Tomczak.kimberly@epa.gov

#### Tomczak, Kimberly

From:

Crane, John P < john.p.crane@zoetis.com>

Sent:

Thursday, August 30, 2018 9:02 AM

To:

Tomczak, Kimberly

Cc:

Harmer, Jennifer; Bauman, Michael; Ho, Kanoelehua

Subject:

RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi John.

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

Regards,

Innel willy Lannevak, Late Seminest

US Environmental Projection Agency, Region 3 Pesticides Section of Forsyth St. SW. Atlanta, 15 V 30 303 Phone: 404,562,8287

Limith Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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FOR ANIMALL AND THE FOR YOU.

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

**To:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>> **Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kumberly Tomezak, 15te Scienus: US Environmental Protection Agency, Region 3 Pesticides Section 61 Forsyth St. SW Adama, GA 200303 Phone: 404,362,8987 Famail: Tomezak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kimberly Tonazak, Lde Scientsi US Environmental Protection Agency, Region 3 Pesneides Section 61 Forsyth St. SW Allama, GA 3030a Phone: 404.562.8987 Email: Tomczak, kimberly@cpa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

**Sent:** Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

#### Regards,

Kumberly Fourczak, Life Sciences

I Schrydenmenna Protection Agency Region 1
Pesticides Section

Of Forsyth St. SW Adams, CA. (2010)
Phone: 404.262.8983
Funally Tomezak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crape | Grape | Grape | Grape | Cohn.p.crane@zoetis.com | Subject: Grape | Grape |

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Sebley, Christopher H < christopher.sebley@zoetis.com>; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

#### Regards,

Kimberly Tomczak, Life Scientist 1.8 Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SAV Atlanta, CAN 30803 Phone: 40 Löbb 2.8987 Linuill: Tomczak, kimberly@cpa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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#### Tomczak, Kimberly

From:

Sebley, Christopher H <christopher.sebley@zoetis.com>

Sent:

Wednesday, September 12, 2018 12:54 PM

To:

Tomczak, Kimberly

Cc:

Bauman, Michael; Ho, Kanoelehua

Subject:

RE: Entry # U16-10064192

#### Kimberly,

The cases of product are at the re-labelling site in Atlanta. Labels will be sent next week from the manufacturer. We expect the relabeling to be complete October 4<sup>th</sup> when we will send you pictures of the relabeled product and any other documentation you require.

#### Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

#### FOR ANIMALS. FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 12, 2018 10:30 AM

To: Sebley, Christopher H

**Cc:** Bauman, Michael; Ho, Kanoelehua **Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Good morning,

What is the status on this shipment? Has it been relabeled?

#### Regards,

Kimberly Comezak, Lafe Scientist US Environmental Protection Agency, Region 1 Pesticides Section of Forsyth St. SM. Atlanta, vs V 20068 Phone: 104,562,8987

Email: Lomezak knuderica epagos

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, August 03, 2018 10:58 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

Yes I have contacted Contrpac Inc., and they have provided a quote to me for the re-labelling work. I have explained the nature of the product and they are ok with performing this task.

I explained that we will need photographs and/ or an on-site visit from the EPA or their representative.

#### Regards,

Chris Sebley | Senior Manager | Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

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FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Friday, August 03, 2018 10:53 AM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

Is Contrapac, Inc. aware that you plan to relabel the product there and are they okay that you are taking it there?

#### Thank you,

Kumbern Touncyak, Life Sevential US Environmental Protection Agency, Region 1 Pesticides Sections of Forseth Sc SM Adamus, CA 30303

Phone: 104,562,8987

hamil: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

**Sent:** Friday, August 03, 2018 8:54 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov> Subject: RE: Entry # U16-10064192

Kimberly,

This arrived at the Marietta, GA warehouse on 5/15 and was received into our inventory system on 5/29.

#### Regards,

Chris Seblev | Senior Manager | Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Friday, August 03, 2018 7:08 AM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

What was the date the Inovotabs were transported to Zoetis's facility in Marietta, Georgia from the Port?

#### Thank you,

Kumberly Connexale, Life Scientise US Environmental Protection Agency, Region 4 Pesticides Section

61 Forsyth St. SW Adams, GA 30303

Phone: 104,562,8987

Email. Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, August 01, 2018 4:37 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

The label is on the case. The product arrived at the port of Charleston on April 27<sup>th</sup> 2018.

Chris Sebley i Seniar Manage: Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

FOR ANIMALS. FOR HEALTH, FOR YOU

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 01, 2018 12:58 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

What is the weight of the containers you are holding? Are they supersacks, containers or drums?

Just want to make sure I get the correct information in the Stop, Sale Order.

Thank you,

Kimbern Tomezak, Life Scienist US Environmental Protection Agency, Region 1 Pesticides Sections 61 Forsuli St. SW Atlanta, GA 30303. Phone: 104.,352.8987

Finall: Tomczak.kimberly@cpa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 26, 2018 4:12 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Subject: RE: Entry # U16-10064192

Kimberly,

I have located a company in the Atlanta area with EPA Establishment #: 52270-GA-01 that I will use to relabel the product.

Contrapac Inc

Labeling Location: 675 Great Southwest Parkway, Atlanta, GA 30336

EPA Est. Number: 52270-GA-01

It is located 25 miles from the current location of the product in Marietta, GA.

Please let me know if this is acceptable?

Regards,

Chris Sebiey | Semor Manager, Procurement

Zoetis Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

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FOR ANIMALS, FOR HEALTH, FOR YOU,

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, July 25, 2018 4:28 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

Do you have the EPA Establishment Number for the facility? I'm not familiar with the EPA Registry ID.

Thank you,

Kimberly Tomezak, Life Scientist

1.8 Environmental Progenies, Agency, Region 1.

Pesicide System

61 Forsith St. SW Albana, CA 30303

Phone: 10 L. R. 2.8987.

Fanal. Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 25, 2018 4:26 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Entry # U16-10064192

Kimberly,

This is good news that we can re-label in the USA.

We would like to use the Zoetis Marietta Logistics Center EPA Registry ID: 110070021744. Details below. The product is also located here and is "on-hold".

## Regards,

Chris Sebley School

#### Regards,

Chris Sebley | Semot Manager Procurement

Zoetis | Global Biodevices and Automation: 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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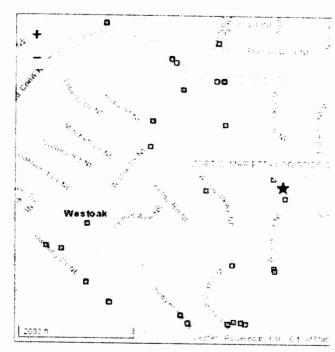
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FOR ANIMALS, FOR HEALTH, FOR YOU.

### **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id: 110070021744 1950 WEST OAK CIRCLE

MARIETTA, GA 30062



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- F3 QSMQV
- EBS Eth small Data, Model
- Bb -ecsistal Mode

ALC: NO THE REAL PROPERTY.

#### Legend

- Selected Facility
- EPA Facility of Interest
- □ State/Tribe **Facility of Interest**

The faculty locations displayed come from the FRS Special Coordinates tables. They are the best representative locations for the displayed facilities based on the accuracy of the collection method and quarky assurance checks performed against each light according to the facility of 1997 in which american Casum of 1997 is used to display at coordinates.

#### **Environmental Interests**

Information System	System Facility Marine	biformation System bi/Report Link	Interest Type	Days Source	lass Bodated Date	Supplemental Cover
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Additional EPA Reports Mylinvitationent, Enfantemiest und Compliante. Site Gemographics, Frighty Coundmales Viewer, Environmental future, Magi Viewer, Watershed Reques

#### Standard Industrial Classification Codes (SIC)

Data Source	SIC Code	Остопнов	Primary
NPOES	4225	GENERAL WAREHOUSING AND STORAGE	
		Facility Codes and Flags	
FPA Region		হ্ৰ-	
Dams Number			National Industry Classification System Codes (NAICS)
Congressional	District Number	26	No NAICS Codes returned.
Legislative Dis	inca periodoci		
HUC Code (Wa)	ersting.	DB170001 - UPPER CHATTHHGGGHEE	Facility Mailing Addresses
US Memora Bar	Her Industria		
Federal Facility	,	·	its Facus, Hailing Appresses returned.
Frebut Land			Contacts

Alternative Names

No Contacts returned

**From:** Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, July 25, 2018 1:02 PM

To: Sebley, Christopher H

Subject: RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

Hi Chris,

We will allow you to relabel the product under a Stop, Sale Order. Can you provide me with the name and establishment number for the facility you plan to relabel at?

Once the Order is issued, you will be allowed to move and relabel the product. At this time, the product is to remain where it is currently located.

Thank you,

Kimberly Tomezak, Like Scientist US Environmental Proceetion Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Tuesday, July 24, 2018 4:36 PM

Ennal: Tomczak.kimberly@epa.gov

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** RE: Entry # U16-10064192

Kimberly,

That is good news on the extension.

I have asked the questions below to the supplier, Medentech, in Ireland and will let you know their response.

Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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FOR ANIMALS, FOR HEALTH, FOR YOU.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, July 24, 2018 3:51 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE. This message on clinates from an oxfernal source

#### Hi Christopher,

The Port of Charleston said they could extend the date.

Who is the importer for this shipment? If the company is foreign based, is there a facility in the United States that represents the company? Where is the based at?

#### Regards,

Kimberly Tomezak, Life Scientist US Frivironmental Protection Agency, Region 4 Pesticules Scenor. 61 Forsyth St. SAV Adama, GA 20303 Phone: 404.562.8987 Limit: Tomezak,kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 19, 2018 9:26 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

Thank you for your help this morning.

Please let me know if you are successful extending the Charleston CBP end-date of 7/28/18 to match your end-date of 8/13/18.

#### Regards,

Chris Sebiey | Senior Manager: Procurement

Zoetis | Global Biodevices and Automation 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry



FOR ANIMALS, FOR HEALTH, FOR YOU.

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 3:11 PM

To: Tomczak.kimberly@epa.gov

Cc: Bucher, Art

**Subject:** FW: Entry # U16-10064192

Importance: High

Kimberly,

I was checking the EPA registry and found that the site currently storing the product in question is EPA registered. Is this sufficient to complete the re-labelling here?

#### Regards,

Chris Sebley | Sentor Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

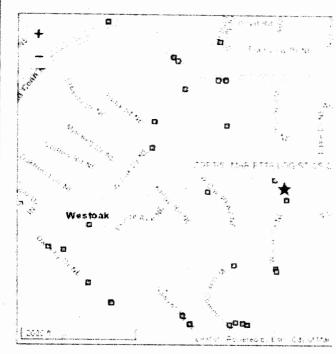


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#### **ZOETIS- MARIETTA LOGISTICS CENTER**

EPA Registry Id: 110070021744

1950 WEST OAK CIRCLE MARIETTA, GA 30062



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#### Legend

- Selected Facility
- D EPA Facility of Interest
- □ State/Tribe Facility of Interest

The facility incetions displayed come from the FPS Spatial Coordinates tables. They are the best representative focations for the displayed facilities based on the accuracy of the collection method and guarth assurance cracks performed against each location. The facility American Calum of 1930 is used to display at coordinates.

#### **Environmental Interests**

Information System	System Facility Name	information System MERCOOK Link	Invironmental	Data Source	Date	Supplemental Emer- Interests.
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#### Standard Industrial Classification Codes (SIC)

Data Source	SIC Code	Description	Primary
NPDE5	4225	GENERAL WAREHOUSING AND STORAGE	

	Facility Codes and Flags	
IPA Region	94	National Industry Classification System Codes (HAICS)
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US Mexico Booster Indicates the Facility Marking Addresses returned. Leideral Easinsy Contacts Errival Land

Alternative Names

tio Contests returned

From: Sebley, Christopher H

Sent: Tuesday, July 17, 2018 8:49 AM

To: 'Tomczak, Kimberly'

**Subject:** RE: Entry # U16-10064192

Kimberly,

I have located a company that will re-label the product in the Atlanta area.

PCA –Atlanta 6300 Boat Rock Blvd Suite E Atlanta, GA 30336

It is 24 miles from the current warehouse in Marietta GA (Zoetis Marietta Logistics Center, 1950 West Oak Circle, Marietta, GA) where the product is located. They will apply to become an EPA registered site to perform this work.

Please let me know as soon as you can if this acceptable. If not I need to start the export process as Customs has a dead line of 7/28/18 for this material to leave the country.

#### Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919,314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

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FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:12 PM

To: Sebley, Christopher H

**Subject:** RE: Entry # U16-10064192

NOTICE. This message originates from an external source.

Hi Chris,

Unfortunately, the product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

#### Regards,

Kunberly Tomezak, Ede Scientist US Environmental Protection Agencyl Region 1 Pesticides Section 61 Forsyth St. SW. Adams, GA 30303 Phone: 404.62.8987 Jamail: Tomezak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 3:05 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

**Subject:** RE: Entry # U16-10064192

Kimberly,

The Kalamazoo site is the closest Zoetis site we have to the warehouse in Marietta, GA that is registered. We would transport it there to be relabeled and then return it per you approval.

Is there a transportation protocol we can follow to satisfy transporting the material this distance?

#### Regards,

Chris Sebiey | Senior Manager Produkement

Zoetis EGlobal Biodevices and Automation: 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

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#### FOR ANIMALS, FOR HEALTH, FOR YOU.

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, July 12, 2018 3:00 PM

To: Sebley, Christopher H

Subject: RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Good afternoon.

The product would need to be relabeled at a facility that is located near where the product is currently being held (Marietta, GA).

#### Regards,

Kumberly Long zak Life Sea ntra US Environmental brotection Agency (Region ) Pesticides Section 61 Forsyth St. SAV Adams, CA 30503 Phone. 404.562.8987 Enrall: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Thursday, July 12, 2018 2:58 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: RE: Entry # U16-10064192

Kimberly,

Zoetis has a site in Kalamazoo MI that I have been told is an EPA registered site. I will find out the details and send them to you.

#### Regards,

Chris Sebley | Senior Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

# zoetis

#### FOR ANIMALS. FOR HEALTH, FOR YOU,

Please consider the environment before printing this email! Thank you.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, July 12, 2018 2:10 PM

**To:** Sebley, Christopher H **Cc:** Doireann O'Brien

Subject: RE: Entry # U16-10064192

NOTICE: This message originates from an external source.

#### Hi Christopher,

If we were to allow you to relabel the product, where would the relabeling take place? The product would need to be relabeled in a EPA Registered Establishment.

#### Thank you,

Kimberk Tomezak, Life Sen mis-

1.8 Environmental Protection Agency Region 1

Pesticides Sections

of Forwell St. SW. Albury, CA. 97867.

Phone: 101, 167, 8981

Januarit Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Wednesday, July 11, 2018 8:45 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

**Subject:** Re: Entry # U16-10064192

Kimberly,

We would get enough labels from the manufacturer that match the master label you have on file. They have revised the label recently to ensure they match.

Regards, Chris Sebley

Sent from my iPhone

On Jul 11, 2018, at 8:38 AM, Tomczak, Kimberly < Tomczak. Kimberly@epa.gov > wrote:

NOTICE: This message originates from an external source.

Hi Chris,

If we allowed you to relabel this product, would you relabel using the last EPA registered label?

Or were you looking to make a notification/amendment change to revise the label?

Thank you,

Kimberly Tomesar, Late Scients: US Environmental Protection, Agency, Region 1: Pesticules Section 61 Forsyth St. SW Admir. GA 30303 Phone: 104.562.8987 Laund: Tomezak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

Sent: Friday, July 06, 2018 10:52 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Doireann O'Brien < dobrien@medentech.com >

**Subject:** Re: Entry # U16-10064192

Good morning,

The product is being held in a Zoetis warehouse in Marietta, GA.

Regards, Chris Sebley

Sent from my iPhone

On Jul 6, 2018, at 5:32 AM, Tomczak, Kimberly < Tomczak. Kimberly@epa.gov > wrote:

NOTICE: This message originates from an external source.

Good morning,

We have received your email and are currently looking into your request.

Where is this shipment currently being held?

Thank you,

Kumberly Tomezak, Lale Scientist US Exvironmental Protection Agency, Region 1 Pesticide, Section 61 Forsyth Sc. SAV Atlanta, GA 20300 Phone: 104,562,8987

finall: Tomczak.kimberly@epa.gov

From: Sebley, Christopher H [mailto:christopher.sebley@zoetis.com]

**Sent:** Monday, July 02, 2018 3:31 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov> **Cc:** Doireann O'Brien < dobrien@medentech.com>

**Subject:** Entry # U16-10064192

Ms. Tomczak,

I am following up on this container load that was refused entry. Entry # U16-10064192.

MBL # HLCUDUB180400955

CARTONS: 15 PALLETS / 1200 CASES - ANTI BACTERIAL TABLETS

ORIGIN - DUBLIN, IRELAND

VSL: PHILADELPHIA EXPRESS 053W

ETD: 415/18

CONTAINER SIZE: CAIU9098991 - 40HC DESTINATION - CHARLESTON, SC

1. In the latter part of May this container was trucked from the port to our warehouse in Marietta GA with no instructions surrounding the "bond" status accompanying it. The container was unloaded and placed in our stock. As of 6/29/18 the stock has been

placed on "hold". However in the interim 48 of the 1200 cases of product was shipped out to an end customer and consumed.

2. The letter attached and a subsequent letter (0322 001) gave the options for destruction of the product or re-export and have the label issue resolved. We would prefer the option to re-export the product. Rather than ship the product back to the manufacturer in Ireland, can these cases be relabeled in an EPA registered facility here in the USA?

Please let us know how to proceed.

#### Regards,

Chris Sebley | Senio: Manager, Procurement

Zoetis | Global Biodevices and Automation | 1040 Swabia Ct, Durham, NC 27703 USA

Office: 919.314.2656 | Mobile: 919.896 4633 | christopher.sebley@zoetis.com

Visit Us: zoetis.com/poultry

#### <image001.gif>

#### Tomczak, Kimberly

From:

Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent:

Wednesday, September 12, 2018 1:02 PM

To:

Tomczak, Kimberly

Cc:

Crane, John P

Subject:

RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope you are doing well! To date, the shipments have not been relabeled. We have updated the label per the SSURO and those labels are currently on order. Once the site receives the updated labels they will initiate relabeling. I will update you once the relabeling activity has been completed.

Please do not hesitate to contact me with any additional questions.

Thanks!

Jennifer

#### Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, September 12, 2018 10:29 AM **To:** Harmer, Jennifer < jennifer.harmer@zoetis.com> **Cc:** Crane, John P < john.p.crane@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Good morning,

What is the status on this shipment? Has it been relabeled?

Regards,

Kimberly Tomezak, Life Seienest US Environmental Protection Agency, Region 3

Pesticides Section

61 Persyth St. SW Atlanta, GA 36305

Phone: 101.562.8957

Limit: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>
Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

#### Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kimberly Tomezak, Life Sciennst US Eavironmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

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#### Tomczak, Kimberly

From:

Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent:

Monday, September 17, 2018 11:27 AM

To:

Tomczak, Kimberly

Cc:

Crane, John P

Subject:

FW: Case No. FIFRA-04-2018-3257

Attachments:

SSURO\_Case FIFRA-04-2018-3257\_13Aug18.pdf

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks!
Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

#### Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

# Regards,

Kimberly Fornezak, Life Scients, US Environmental Protection Agency, Region 3 Posicides Section of Forsith St. SAV Adamo. GA 2030.: Phone: 404.562.8987

Finail: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

< ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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Subject: RE: Case No. FIFRA-04-2018-3257

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Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

## Regards,

Kimberty Tensezak, Life Sciences

I.S. Environmental Protection Agency, Region 4
Pesticides Section

61 Forsyth St. SAV Adamic CA 300903
Phone: 404,562,8987
Finall: Tomczak,kimberty@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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Sent: Thursday, August 23, 2018 4:24 PM

**To:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>> **Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kumberly Tourezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30305 Phone: 404,562 8087

banail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak, Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

**To:** Harmer, Jennifer < jennifer.harmer@zoetis.com > **Cc:** Crane, John P < john.p.crane@zoetis.com >

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

# Regards,

Kunberly Fonezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adanta, GA 30303 Phone. 404.562,8987 Final: Tomczak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

#### Regards,

Knoberty Lornezak, Life Scientist LS Environmental Protection Agency, Region 4 Pesticides Sections of Forwith St. SW Atlanta, GA 50303 Phone, 404,562,8987 Linail: Tomezak,kimberty@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

#### Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<imessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

Regards,

Kimberly Lomezak, Life Scientist 1 S Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adams, GA 30303

Phone: 101.362.8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<imessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

# Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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# Tomczak, Kimberly

From:

Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent:

Monday, September 17, 2018 1:44 PM

To:

Bauman, Michael

Cc:

Crane, John P; Tomczak, Kimberly

Subject:

RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks!

Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow..

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

 Cc: Crane, John P < john.p.crane@zoetis.com> Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are

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Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

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Kunberly Tomezick, Life Scientist U.S. Environmental Procession Agency, Region 1 Pesticides Section 61 Forsyth St. SW, Adama, 6, V 30303 Phone: 104,562,8987

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<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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Regards,

Kimberly Tong zak, Late Securist US Favaroumental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW, Allanda, GA 30203 Phone: 104,562,8787

Linai: Tomczak.kimberly@epa.gov

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Sent: Wednesday, August 29, 2018 1:30 PM

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Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

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Many thanks.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

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#### Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

## Regards,

Kunberty Lomezak, Life Scientist .

LS Fraviournent d Protection Agency, Region a Pesticides Section 61 Forseth St. SW Attanta, GA 30303; Phone: 104.562.8987 html://LTC.Com/Protect/P

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#### Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

# Regards,

Kimberly Foraczak, tafe Segmost US Environmental Protection Agency, Region 4 Pesticides Section 64 Forsyth St. SW. Atlanta, GA 30303 Phone: 404,562,8987

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

tanal: Tomczak.kimberly@epa.gov

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

Regards,

Kimberly Tomezak Life Seconds:

US Environmental Protection Agency, Region 1 Pesticides Section 51 Forsyth St. SAV Adams, CA 36803 Phone: 104,562,8987 Umail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak,Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE. This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

# Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region & Pesticides Section 61 Forsyth St. SW Atlanta, CA 30303 Phone: 104.562.8987 Email: Tomezak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly @epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>; Sebley, Christopher H < <u>christopher.sebley@zoetis.com</u>>; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
Visit Us: zoetis.com

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# Tomczak, Kimberly

From:

Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent:

Wednesday, September 19, 2018 10:43 AM

To:

Tomczak, Kimberly

Cc:

Crane, John P

Subject:

RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for this information! Can you please provide an estimate on timing to amend the SSURO? Do you anticipate that it can be amended in the next week or is this something that will take a significant amount of time (e.g., weeks to months)?

I appreciate your assistance with this!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 9:29 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>
Cc: Crane, John P < john.p.crane@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

We are going to amend the SSURO to allow you to relabel at the other facility listed.

Please be advised that the product cannot be moved or relabeled at the facility until the Amended SSURO is issued.

#### Regards,

Kimberty Fornezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 64 Forsyth St. SW Atlanta, G y 30303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:27 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

Visit Us: zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE. This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

Regards,

Kimberly Tomezak, Late Sciennst

US hardronnicual Protection Agency, Rogert 1

Pestirales Sections

61 Forsyth St. SVI Minuter CA 20003.

Phone: DESGEMA?

Limil: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

## Regards,

Knoberly Tomezak, Lafe Scientist US Frairconnental Protection Agency, Region 1 Pesnerdes Section 61 Forsyth St. 5M. Adama, 6-3 (3030)3. Phone: 101.562.8987

liminit Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov> Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kumberly Fornezak, Life Scienter ( US Environmental Protection Agency, Region ( Pesticides Section of Forsyth St. SW Adamot, GA 30000) Phone: 404,562,8987 Frant: Tomczak, kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

# Regards,

Kumberly Tomezak, Life Scientist US Environmental Protection Agency, Region 3 Pesticistes Section 61 Forsyth St. SW Admit. CLA 30303 Phone: 404.562.838.7 Unual: Tomezak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

## Regards,

Kumberly Tomezak, Life Scientisi US Environmental Protection Agency, Region ? Pestientes Section 61 Forsyth St. SW Adama, CA 30505 Phone: 104,562,8987

Final: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.4857 | jennifer.harmer@zoetis.com

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Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>; Sebley, Christopher H < <u>christopher.sebley@zoetis.com</u>>; James Messina

<imessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

# Regards,

Kumberly Toniczak, Life Scienijsi US Faivironmental Protection Agency, Region 1 Pesticides Section of Forsyth St. 8W Atlanta, CA 30303 Phone: 10 L502.8987

Final: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Sebley, Christopher H < christopher.sebley@zoetis.com>; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on

Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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# Tomczak, Kimberly

From:

Nicola Roche <nicola.roche@kersia-group.com>

Sent:

Tuesday, November 27, 2018 5:43 AM

To:

Tomczak, Kimberly

Subject:

RE: FIFRA-04-2018-3257

Hi Kimberly, Yes thank you, Michael was a great help! I hope you had a wonderful Thanksgiving.

Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ ±353 53 911 7929



HYPREO Kilko' ( Ga antigerm medentech Ga



www.kaisic group cam

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Monday 26 November 2018 18:12

To: Nicola Roche < nicola.roche@kersia-group.com>

Subject: RE: FIFRA-04-2018-3257

Hi Nicola,

I believe Michael Bauman responded to the company while I was out of the office.

Please let me know if you have any additional questions.

#### Regards,

Kunberly Toniczak, 15le Scientsi US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adamia, GA 30303 Phone: 404,562,8987 From: Nicola Roche <nicola.roche@kersia-group.com>

Sent: Tuesday, November 20, 2018 10:10 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: [SPAM-Sender] FIFRA-04-2018-3257

Good afternoon Kimberly,

I hope my mail finds you well.

At the moment I am trying to schedule the return of goods from ContraPac to Ireland.

We have forwarded revised packing lists and an invoice for the return leg, however I am not sure if we need approval from the EPA to move the goods?

The attached only states a letter must be provided when goods are received into our warehouse in Wexford.

The broker has asked the following:

# Will this be under US Customs/FDA supervision i.e. they need to be present when container is loaded?

If you could help clarify whether we can just ship the goods or whether we need an EPA official present, I would really be very grateful.

Thank you for your help Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



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antigerm medentech G3



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# Tomczak, Kimberly

From:

Nicola Roche <nicola.roche@kersia-group.com>

Sent:

Tuesday, November 27, 2018 5:43 AM

To:

Tomczak, Kimberly

Subject:

RE: FIFRA-04-2018-3257

Hi Kimberly, Yes thank you, Michael was a great help! I hope you had a wonderful Thanksgiving.

Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications, Manager



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antigerm medentech GB

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www.kersia group.com

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Monday 26 November 2018 18:12

To: Nicola Roche <nicola.roche@kersia-group.com>

Subject: RE: FIFRA-04-2018-3257

Hi Nicola,

I believe Michael Bauman responded to the company while I was out of the office.

Please let me know if you have any additional questions.

#### Regards,

Kumberly Temezak, Life Sciencist US Environmental Projection Agency, Region 4 Pesticides Section 61 Forsyll St. SW. Alkinia, C. v. 30303 Phone: 404.052.8087

Finali: Tomczak.kimberly@epa.gov

From: Nicola Roche < nicola.roche@kersia-group.com>

Sent: Tuesday, November 20, 2018 10:10 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: [SPAM-Sender] FIFRA-04-2018-3257

Good afternoon Kimberly,

I hope my mail finds you well.

At the moment I am trying to schedule the return of goods from ContraPac to Ireland.

We have forwarded revised packing lists and an invoice for the return leg, however I am not sure if we need approval from the EPA to move the goods?

The attached only states a letter must be provided when goods are received into our warehouse in Wexford.

The broker has asked the following:

# Will this be under US Customs/FDA supervision i.e. they need to be present when container is loaded?

If you could help clarify whether we can just ship the goods or whether we need an EPA official present, I would really be very grateful.

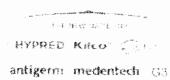
Thank you for your help Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929







# Tomczak, Kimberly

Erom.	
FIOIN.	

Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent:

Monday, November 12, 2018 7:49 AM

To:

Tomczak, Kimberly; Crane, John P

Cc:

Bauman, Michael; Ho, Kanoelehua

Subject:

RE: Case No. FIFRA-04-2018-3257

Hi Kim,

I received the letter last Thursday informing Zoetis that we can export the two shipments listed in the SSURO. Within the SSURO, there is a request for a letter confirming that the product has been exported to and received at Medentech in Ireland. Can you please confirm that a single letter confirming both export and receipt will suffice or if the request is for two separate letters, one confirming export and another confirming receipt?

Thanks in advance for your assistance with this!

Regards,

Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 06, 2018 7:04 AM

**To:** Harmer, Jennifer <jennifer.harmer@zoetis.com>; Crane, John P <john.p.crane@zoetis.com> **Cc:** Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

We hope to get a letter out to you shortly in regards to the next step.

If you do not receive anything by close of business on Thursday, November 8, please let me know.

Regards,

Kimberty Tobiczak, Life Scientist US Environmental Protection Agency, Region 3 Pesticides Section 61 Forsyth St. SW. Adams, GA 30305 Phone: 1045/02/8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 05, 2018 4:11 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > **Cc:** Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

John Crane is out of the office this week and so I am following up on the below shipment. Can you please advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks in advance!
Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, October 31, 2018 4:03 PM **To:** Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

I am in discussions with my Supervisor about the steps that will need to be taken to get these shipments exported.

I will be in touch with you tomorrow or Friday.

Regards,

Kunberly Comezak, Life Scientisi US Environmental Protection Agency, Region 1 Pesicides Section Of Forsuli St. SW Adams, GA 30503 Phone: 104,562,8987

final: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Tuesday, October 30, 2018 6:47 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

**Subject:** RE: Case No. FIFRA-04-2018-3257

Good morning Kimberly:

Are you able to advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

### Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Tuesday, October 23, 2018 3:33 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

Thank you for your message. We look forward to hearing back from you.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Tuesday, October 23, 2018 3:16 PM **To:** Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

### Good afternoon,

I have reached out to my Supervisor in regards to this request and will get back in touch with you as soon as I can.

The shipment should remain where it is currently located until you hear back from the EPA Region 4 office.

#### Thank you,

Kumberly Tomezak, Life Scientist US Environmental Protection Agency Region 1 Pesticides Section of Forsyth St. SW Adamta, GA 30303 Phone: 404,562,8987

hamai: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

#### Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

#### Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

#### Thank you,

Kumberty Tourezak, Lafe Scienast US Environmental Protection Agency, Region 4 Pesticides Section 64 Forsyth St. SAV Adamta, GA 30303 Phone: 404,562,8987

tanail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<<u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

Regards,

Kimberly Tomezak, Life Scienus US Environmental Projection Agency, Region 4 Pesticides Section Of Forsyth St. SW. Minnta, CA 30303

Phone: 401.562.8987

Finalt: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

**Cc:** Crane, John P < <u>iohn.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

#### Thank you,

Kunberly Tomezak, Late Scienisi US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, CA 3050.3 Phone: 404.562.8987 Limah Tomezak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

**Sent:** Monday, September 17, 2018 11:54 AM **To:** Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

#### Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow..

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

**Sent:** Monday, September 17, 2018 11:36 AM **To:** Bauman, Michael < <a href="mailto:bauman.michael@epa.gov">bauman, Michael < a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer
Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM
To: Crane, John P < john.p.crane@zoetis.com >

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

Regards,

Kimberly Tomezak, Life Seientst US Environmental Protection Agency, Region 4 Pesticides Section of Forsyth St. SW. Athana, GA 30303

Phone: 104.362.8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM

To: Crane, John P < john.p.crane@zoetis.com >

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

#### Regards,

Kunberly Cooceal, Life Scientist 1-8 Environmental Projection, Agency, Region & Pesticides Section 64 Forsyth St. SW. Adamb. GA 30303 Phone: 104.562.8987 Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Crane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you are not an addressee, please inform the sender immediately.

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a> Cc: Crane, John P < <a href="mailto:jennifer.harmer@zoetis.com">john.p.crane@zoetis.com</a> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

### Regards,

Kimberly Fornezak, Life Scienust US Environmental Protection Agency, Region 4 Pesticides Section of Forsyth, St. SW Atlanta, CA 30303 Phone: 404.562.8987 Email: Tomczak, kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]
Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

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Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kimberly Teanezak, Life Securist
1-8 Environmental Protection Agency, Region 1-,
Pesticides Section
61 Forsyth St. SW Atlanta, GA 30303
Phone: 404.562.8987
Enrich: Tomczak, kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This massage originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

# Regards,

Kumberly Vomezak, Life Scientist US Environmental Protection Agency, Region 3 Pesticides Section 61 Forsyth St. SW Affanta, GA 30303 Phone: 404,562,8987

Tanzal: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

#### Regards,

Kunberly Lomezak, Life Scientist US Laviconmental Protection Agency, Region 4 Pesticides Section 64 Forsath St. SW Atlanta, GA 30303 Phone: 104,562,8987

Linan. Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

**Sent:** Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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# Tomczak, Kimberly

From:

Bauman, Michael

Sent:

Wednesday, November 21, 2018 9:38 AM

To:

Crane, John P; Nicola Roche

Cc:

Harmer, Jennifer; Tomczak, Kimberly; Ho, Kanoelehua

Subject:

RE: Case No. FIFRA-04-2018-3257

Good morning,

That is correct.

Regards, Michael

Tel: 404-562-8962 | Email: bauman.michael@epa.gov

From: Crane, John P < john.p.crane@zoetis.com> Sent: Wednesday, November 21, 2018 8:55 AM

To: Bauman, Michael <br/>
<br/>
Sauman.michael@epa.gov>; Nicola Roche <nroche@medentech.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Good morning Michael.

All noted.

Do I interpret correctly therefore that an EPA official does not need to be present when the container is loaded for export at Contrapac (for export back to the Medentech facility in Ireland)?

Thank you.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you are not an addressee, please inform the sender immediately.

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Wednesday, November 21, 2018 8:47 AM

To: Crane, John P < <u>john.p.crane@zoetis.com</u>>; Nicola Roche < <u>nroche@medentech.com</u>>

Cc: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning,

Please note a correction in the second paragraph below:

As part of the verification requested for when the shipment arrives at Medentech in Ireland (from the letter stamped November 5, 2018), please provide a signed certification from Zoetis' chief executive officer (CEO) or other authorized official of the company stating the quantity of product exported, the date and location of export and the date and location of receipt at Medentech.

Please note that the EPA may decide to conduct an inspection at Contrapac's facility to confirm and verify that the product has been exported.

Regards, Michael

Tel: 404-562-8962 | Email: bauman.michael@epa.gov

From: Crane, John P < john.p.crane@zoetis.com > Sent: Tuesday, November 20, 2018 1:40 PM
To: Bauman, Michael < bauman.michael@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Michael.

Regards, John

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Tuesday, November 20, 2018 1:23 PM

To: Crane, John P < john.p.crane@zoetis.com >; Nicola Roche < nroche@medentech.com >

Cc: Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer < jennifer.harmer@zoetis.com >; Tomczak, Kimberly

<Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

# Good afternoon,

I have forwarded on your and Nicole's questions for a response and will provide the additional information when it is available.

Regards, Michael

Tel: 404-562-8962 | Email: bauman.michael@epa.gov

From: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Sent: Tuesday, November 20, 2018 12:56 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kim:

Jennifer is off on vacation this week hence the email from me.

Medentech is now ready to ship these two shipments back to Ireland. The broker has asked the question whether an EPA official needs to be present when the container is loaded at Contrapac. The attached EPA letter states "The EPA Region 4 is hereby allowing Zoetis to export the products back to a Medentech facility in Ireland." There is no mention of this needing the oversight of an EPA official. Please can you confirm that no EPA official needs to be present when the container is loaded for export.

Thank you.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 13, 2018 7:15 AM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>; Crane, John P < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>;

Cc: Bauman, Michael < <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>>; Ho, Kanoelehua < <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message onlyingtes from an external course.

Hi Jennifer,

You can send one letter that states both pieces of information.

Please let me know if you have any additional questions.

Regards,

Kumberly Tounczak, Lafe Scientist US Environmental Protection Agency, Region 1 Pesticules Section 61 Forsyth St. SW Atlanta, GA 20303 Phone, 404,562 8987 Email: Tomczak,kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 12, 2018 7:49 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > **Cc:** Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

I received the letter last Thursday informing Zoetis that we can export the two shipments listed in the SSURO. Within the SSURO, there is a request for a letter confirming that the product has been exported to and received at Medentech in Ireland. Can you please confirm that a single letter confirming both export and receipt will suffice or if the request is for two separate letters, one confirming export and another confirming receipt?

Thanks in advance for your assistance with this!

Regards,

Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 06, 2018 7:04 AM

**To:** Harmer, Jennifer < <u>iennifer.harmer@zoetis.com</u>>; Crane, John P < <u>iohn.p.crane@zoetis.com</u>> **Cc:** Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua < <u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer.

We hope to get a letter out to you shortly in regards to the next step.

If you do not receive anything by close of business on Thursday, November 8, please let me know.

Regards,

Kimberly Tomezak, Life Scientsi US Lawironmiental Protection Asymey, Region 1 Pesticides Section 1 64 Porsvili St. SW Allania, GA 30303 Phone: 40 L56/2/8087

Limil: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Sent: Monday, November 05, 2018 4:11 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>>; Crane, John P < <u>john.p.crane@zoetis.com</u>> **Cc:** Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua < <u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

John Crane is out of the office this week and so I am following up on the below shipment. Can you please advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks in advance! Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, October 31, 2018 4:03 PM **To:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Cc: Bauman, Michael <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

I am in discussions with my Supervisor about the steps that will need to be taken to get these shipments exported.

I will be in touch with you tomorrow or Friday.

Regards,

Kumberly Tomezak, Life Seremise

US Environmental Protection Agency, Region 1

Pesticides Section

61 Forsyll, St. SW, Allama, 37A 36302.

Phone: 101.362-8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Tuesday, October 30, 2018 6:47 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Good morning Kimberly:

Are you able to advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Tuesday, October 23, 2018 3:33 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

Thank you for your message. We look forward to hearing back from you.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, October 23, 2018 3:16 PM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

#### Good afternoon.

I have reached out to my Supervisor in regards to this request and will get back in touch with you as soon as I can.

The shipment should remain where it is currently located until you hear back from the EPA Region 4 office.

# Thank you,

Knuberly Tomezak, Life Scientist US Environmental Protection Agency, Region & Pesticides Section 61 Forsyth St. SW Adamia, GA 30303 Phone: 104,562,8987

Linait: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

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# Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

#### Thank you,

Kimberly Louiszak, Life Science) US Environmental Protection Agency, Region a Pesticides Section 61 Forsyth St. SW Atlanta, GA 30363 Phone: 404-562,8987

Finail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<<u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

#### Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

### Regards,

Kumberly Tomezak, Life Scienusi US Environmental Protection Agency, Region 1 Pesticides Scenon 61 Forsyth St. SW Adama, GA 30303 Phone: 104,562,8987 Email: Tomezak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly < Tomczak, Kimberly@epa.gov >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

#### Thank you,

Kimberty Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section of Forsyth St. SAV Atlanta, GA 30302. Phone: 404.562.8987 Final: Tomezak,kimberty@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>; Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

### Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow..

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM
To: Bauman, Michael < bauman.michael@epa.gov >
Cc: Crane, John P < john.p.crane@zoetis.com >
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer Jennifer C. Harmer

Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < jennifer.harmer@zoetis.com</a>>; Bauman, Michael < <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

#### Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. 5W Adamia, GA 30303 Phone: 404.562.8987 Limil: Tomezak,kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 30, 2018 8:04 AM **To:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

### Regards,

Kimberly Fornezak, Life Scientist US Environmental Protection Agency, Region ( Pesticides Section of Forsyth St. SW Atlanta, GA 30302 Phone: 104,562,8987 Email: Tomezak,kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

# Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

**To:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

### Regards,

Kumberty Founczak, Life Scientisi US Environmental Protection Agency, Region 1 Pesucides Section 64 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987 Email: Tomczak,kimberty@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kunberly Tomezak, Life Scienusi US Environmental Protection Agency, Region 1 Pesticides Section

of Forsyth St. SW Adama, GA 30303

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the

pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>
Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

# Regards,

Kumberly Tomezak, Lafe Scientiss US Environmental Protection Agency, Region 1 — Pesticides Section 61 Forsyth St. SW Atlanta, GA 50303 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's

establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

Regards,

Kimberly Tomezak, Life Semant US Environmental Protection Agency, Region 1 Pesticides Section of Forsyth St. SW Adams, GA 50303 Phone: 404,562,8987

Limail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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# Tomczak, Kimberly

From:

Nicola Roche <nicola.roche@kersia-group.com>

Sent:

Wednesday, December 19, 2018 10:28 AM

To:

Tomczak, Kimberly; ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc:

Bauman, Michael: Ho, Kanoelehua

Subject:

RE: U16-10064192 and U16-10084042

Attachments:

Case No FIFRA-04-2018-3257.pdf

#### Hi Kimberly,

I have been advised by the ACE director of import, that there is a discrepancy with regard to the attached letter. The entry numbers U16 1006419-2 and U16-1008404-2 must appear on the letter along with our company name, Medentech as the exporter of the goods.

I understand that it is not your area, but I would sincerely appreciate that between yourself and Esmeralda I can be guided on this matter.

Everyone seems to have their own procedure and I just want to get move the goods with the correct documentation.

My sincere apologies.

Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



THE MELL DOMESTIC HYPRED KIKUT TO T antigerm medentech G3



www.kersia.group.com

From: Patti Cordo <pcordo@americancargoexpress.com>

Sent: Wednesday 19 December 2018 14:58

To: Jerina Morris < imorris@AmericanCargoExpress.com >; Nicola Roche < nicola.roche@kersia-group.com >; Greg Low

<greglow@comcast.net>

Cc: Sinead Walsh < sinead.walsh@kersia-group.com >; Debra Fierro < dfierro@contrapac.com >; Peter Fierro

<pfierro@contrapac.com>; Mark Leonard < Mark.Leonard@hornerd.ie>

Subject: RE: RETURN TO IRELAND -MEDENTECH

## Nicola

What are you doing to rectify the discrepancy that the Customs Entry and the EPA letter? Did you speak to EPA to get this corrected?

This is a huge problem as the notice of redelivery issued by Customs is passed date and the EPA letter is not to Medentech

Nor does it reference an entry number. This must be resolved prior to export

Regards, Patti

Patti Cordo

Director of Import ACE USA & Canada American Cargo Express **New Jersey Operations** 2345 Vauxhall Rd Union, NJ 07083

Tel: 908-351-3400 x 3026

Fax: 908-289-2490

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From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Tuesday 18 December 2018 17:18 To: ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Nicola Roche

<nicola.roche@kersia-group.com>

Subject: U16-10064192 and U16-10084042

Importance: High

Good afternoon,

The importer for Entry U16-10064192 and U16-10084042 has decided to export these shipments. We had communicated earlier this year about these shipments (see emails on July 25, 2018).

The attached letter allows the company to export the products. Can you provide information to the broker on what other documents are needed to export the two shipments? The broker has been copied on the email.

Thank you for your assistance,

Kimberk Longezak, Life Scientist US Luvironmental Protection Agency, Region 1 Pesticides Science 61 Forsyth St. SAV Adamia, GA 30303 Phone: 404.502.8987 Email: Tomczak, kimberly@epa.gov

From: Nicola Roche <nicola.roche@kersia-group.com>

Sent: Monday, December 17, 2018 11:34 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Subject: FIFRA-04-2018-3257

Importance: High

Good afternoon Kimberly, I hope my mail finds you well.

This query is with regard to FIFRA-04-2018-3257.

We have been trying to consolidate both consignments into a high cubed container to return the goods as promptly as possible to Medentech.

However, the export company used by our carriers have advised that we can only move the goods under CBP supervision. The attached CBP form is related to the first shipment.

I have forwarded your attached letter of release and advised supervision is not required.

The export company believes I need additional clearance from the EPA and at this point I really do not know what that is.

I sincerely apologise for contacting you, but if you can help at all I would be extremely grateful.

My very best regards Nicola

# Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



HABBED KHED. Sen.

antigerm medentech 03



www.kersic aroupliam

From: Mark Leonard < Mark. Leonard@hornerd.ie>

Sent: Monday 17 December 2018 15:42

To: Nicola Roche < nicola.roche@kersia-group.com >; Neil Horner < Neil.Horner@hornerd.ie >

Cc: Sinead Walsh < sinead.walsh@kersia-group.com > Subject: RE: RETURN TO IRELAND -MEDENTECH

Hi Nicola,

our agents have advised:

"this is rejected Merchandise to be returned under CBP supervision

Note you will need to contact Nicola Roche at Medentech see attached

Until Medentech have resolved the outstanding issues we cannot proceed with the Return

Thanks

Kind Regards, Mark.



#### **HORNER AGENCIES LTD.,**

Registered Office : Unit 6, 21 Beechwood Close, Boghall Road, Bray, Co. Wicklow, A98 AN81, IRELAND.

Registered in Dublin, Ireland No. 431611.

Main Tel: 00-353-1-2137940 / Fax: 00-353-1-2022011.

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<ACE SLI -revised Aug2018.xls>

# Tomczak, Kimberly

From:

Crane, John P <john.p.crane@zoetis.com>

Sent:

Friday, December 28, 2018 12:04 PM

To:

Tomczak, Kimberly

Cc:

Bauman, Michael; Ho, Kanoelehua; Harmer, Jennifer

Subject:

RE: Case No. FIFRA-04-2018-3257

Hi Kim:

Yes, Medentech is taking responsibility for exporting the product back to their plant in Ireland. I have no problem with you keeping the revised letter addressed to us (Zoetis). It can come to me at the address below.

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Friday, December 28, 2018 11:02 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Importance: High

NOTICE: This message originates from an external source

Hi John and Jennifer,

I have been notified that the export letter needs to state that Medentech is responsible for exporting the products not Zoetis. Is Medentech responsible for the export of these products?

When we send out the revised letter, should it still be addressed to you?

#### Thank you,

Kimberty Tomeznik, Life Sciennel US Environmental Protection Agency, Region I Pesticides Section 61 Forsyth St. SW. Atlanta, CA 30302 Phone: 404,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Sent: Tuesday, November 20, 2018 12:56 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kim:

Jennifer is off on vacation this week hence the email from me.

Medentech is now ready to ship these two shipments back to Ireland. The broker has asked the question whether an EPA official needs to be present when the container is loaded at Contrapac. The attached EPA letter states "The EPA Region 4 is hereby allowing Zoetis to export the products back to a Medentech facility in Ireland." There is no mention of this needing the oversight of an EPA official. Please can you confirm that no EPA official needs to be present when the container is loaded for export.

Thank you.

Best regards, John

John P. Crane
Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269 259 2008 | Coll. 269 760 1241 | John P.

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 13, 2018 7:15 AM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>; Crane, John P < <a href="mailto:jennifer.harmer@zoetis.com">john.p.crane@zoetis.com</a>>> Cc: Bauman, Michael < <a href="mailto:bauman.michael@epa.gov">jennifer.harmer@zoetis.com</a>>; Ho, Kanoelehua < <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a> <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

You can send one letter that states both pieces of information.

Please let me know if you have any additional questions.

Regards,

Kunberly Tomezak, Lale Scientist US Environmental Protection Agency, Region & Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987

t.mait: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 12, 2018 7:49 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

I received the letter last Thursday informing Zoetis that we can export the two shipments listed in the SSURO. Within the SSURO, there is a request for a letter confirming that the product has been exported to and received at Medentech in Ireland. Can you please confirm that a single letter confirming both export and receipt will suffice or if the request is for two separate letters, one confirming export and another confirming receipt?

Thanks in advance for your assistance with this!

Regards,

Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 06, 2018 7:04 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Crane, John P < john.p.crane@zoetis.com >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua@epa.gov > Subject RF. Core No. 5150A 04 2010 2017

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

We hope to get a letter out to you shortly in regards to the next step.

If you do not receive anything by close of business on Thursday, November 8, please let me know.

### Regards,

Kumberly Fornezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 51 Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987 Email: Tomczak,kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 05, 2018 4:11 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > **Cc:** Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

John Crane is out of the office this week and so I am following up on the below shipment. Can you please advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks in advance!
Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, October 31, 2018 4:03 PM **To:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

I am in discussions with my Supervisor about the steps that will need to be taken to get these shipments exported.

### I will be in touch with you tomorrow or Friday.

#### Regards,

Kunberty Lomezak, Life Scientis: US Environmental Protection Agency, Region 3 Pesticides Section 61 Forsyth St. SW, Atlanta, GA 30303 Phone: 404-562,8987

1 1101101 101 1012 10120

Limil: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Tuesday, October 30, 2018 6:47 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Good morning Kimberly:

Are you able to advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Tuesday, October 23, 2018 3:33 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

Thank you for your message. We look forward to hearing back from you.

#### Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, October 23, 2018 3:16 PM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua<br/>
<a href="mailto:kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

#### Good afternoon,

I have reached out to my Supervisor in regards to this request and will get back in touch with you as soon as I can.

The shipment should remain where it is currently located until you hear back from the EPA Region 4 office.

#### Thank you,

Kumberly Tomezak, Life Scienusi US Environmental Projection Agency, Region 1 Pesticides Section 61 Forsyth St. SM, Atlanta, GA 30203. Phone: 101,562,8987

Linail: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks!

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

#### Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

#### Thank you,

Kunberly Tomezak, Life Scienust US Environmental Protection Agency, Region 1 Pesneides Section 64 Porsyth Sc SW Atlanta, GA 30303 Phone: 104.562.8987

hamil: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

Regards,

Kumberly Lomezak, Late Scientist U.S.Linvironmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW. Atlanta, CvX 30303 Phone: 404.562.8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Bauman, Michael <br/>
<br/>
| Sauman.michael@epa.gov

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>> Subject: RE: Case No. FIFRA-04-2018-3257

#### Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

Thank you,

Kimberly Tomezak, Life Scienust US Environmental Protection Agency, Region 4 Pesticides Section 61 Vorseth St. SW Adanta, GA 30302

Phone: 104.562.8987

Limil: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael <bauman.michael@epa.gov>

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>>; Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow..

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM
To: Bauman, Michael < bauman.michael@epa.gov >
Cc: Crane, John P < john.p.crane@zoetis.com >
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 jennifer.harmer@zoetis.com

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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>
Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

#### Regards,

Kimberly Founczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section of Forsyth St. SW Adapta, GA 3030's Phone: 104,362,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

## Regards,

Kimberly Tomczak, Life Scientist US Lawronmental Protection Agency, Region 4 Pesticides Sections of Forsyth St. SW Atlanta, GA 20003 Phone: 404.062.8987 Franil: Tomczak, kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>> **Cc:** Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Grane Director, US Regulatory Affairs

Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com> Cc: Crane, John P < john.p.crane@zoetis.com> Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kumberly Lomezak, Life Sea mist 1.8 Environmental Protection Agency, Region 3. Pesticides Section: of Forsyth St. SW. Atlanta, GA 30030 v. Phone: 101,562,8987

Languil: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

#### Regards,

Kimberly Tomezak, Life Scienust US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30303 Phone: 104.562.8987

hamail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

### Regards,

Kumberty Foruczak, Life Scientisi US Environmental Protection Agency, Region F Pesnedes Section of Forsyth St. SW Atlanta CA 30202 Phone: 104.562.8987

Funal: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

#### Regards,

Kimberly Tomozak, Lale Scientist 1.5 Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adama, GA 30303 Phone: 101,562,8987 Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20th for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.4857 | jennifer.harmer@zoetis.com

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## Tomczak, Kimberly

From:

Nicola Roche <nicola.roche@kersia-group.com>

Sent:

Tuesday, January 29, 2019 3:48 AM

To:

Tomczak, Kimberly; ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc:

Bauman, Michael; Ho, Kanoelehua

Subject:

RE: U16-10064192 and U16-10084042

Thank you Kimberly,
I will get back to our broker straight away!

Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



HYPRED KIKO (D) e n

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From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Monday 28 January 2019 20:29

To: Nicola Roche <nicola.roche@kersia-group.com>; ESMERALDA.MARTINEZ@cbp.dhs.gov Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>

Subject: RE: U16-10064192 and U16-10084042

Good afternoon,

The broker may need to submit documents to CBP to export the shipments but nothing else is required from EPA to export the products.

Regards,

Kimberty Lomezak, Life Scienist US Environmental Protection Agency, Region J. Pesticides Section 61 Forsyth St. SW. Albana, GA 30303 Phone: 404,362-8987

Famil: Tomczak.kimberly@epa.gov

From: Nicola Roche < nicola.roche@kersia-group.com >

Sent: Monday, January 28, 2019 11:35 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; ESMERALDA.MARTINEZ@cbp.dhs.gov **Cc:** Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

**Subject:** RE: U16-10064192 and U16-10084042

Importance: High

Hi Kimberly,

Happy to advise that we did indeed receive the letter.

However, our broker has advised that we are missing a release form relating to U16-10084042.

If the attached is enough to release the goods for customs purposes, I am happy to move the goods as soon as possible. Would it be possible to confirm the letter is the only requirement to move the goods?

Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



HYPRED KILO COLL

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198 M. O. BATELLEY



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From: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Sent: Monday 28 January 2019 15:44

To: Nicola Roche <nicola.roche@kersia-group.com>; ESMERALDA.MARTINEZ@cbp.dhs.gov
Cc: Bauman, Michael <br/>
bauman.michael@epa.gov>; Ho, Kanoelehua <no.kanoelehua@epa.gov>

Subject: RE: U16-10064192 and U16-10084042

Hi Nicola,

The revised export letter was sent to Zoetis on December 28, 2018.

Please let me know if it was not received.

Regards,

Kumberly Tomezak, Lak Scienis.

US Favoronmental Protection Agency, Region 1

Pesticides Sertion

of Forsith St. SW. Mianta GA 30502

Phone: 101.562.8087

Limit Tomczak.kimberly@epa.gov

From: Nicola Roche < nicola.roche@kersia-group.com>

Sent: Monday, January 07, 2019 10:18 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; ESMERALDA.MARTINEZ@cbp.dhs.gov Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: U16-10064192 and U16-10084042

Hi Kimberly,

I hope you are keeping well.

Can you advise whether the revised release letter is now available?

Kind regards Nicola

#### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



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From: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Sent: Friday 28 December 2018 17:36

To: Nicola Roche < nicola.roche@kersia-group.com >; ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: U16-10064192 and U16-10084042

Good morning,

We hope to get a revised letter to Zoetis shortly with the two additional pieces of information.

Regards,

Kimbert: Fornezak, Life Scienusi

1.8 Environmental Protection Agency, Region 1.

Pesticides Section

of Forsyth St. SW Atlanta, CA 30303

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Nicola Roche < nicola.roche@kersia-group.com > Sent: Wednesday, December 19, 2018 10:28 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; ESMERALDA.MARTINEZ@cbp.dhs.gov Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

**Subject:** RE: U16-10064192 and U16-10084042

Hi Kimberly,

I have been advised by the ACE director of import, that there is a discrepancy with regard to the attached letter. The entry numbers U16 1006419-2 and U16-1008404-2 must appear on the letter along with our company name, Medentech as the exporter of the goods.

I understand that it is not your area, but I would sincerely appreciate that between yourself and Esmeralda I can be guided on this matter.

Everyone seems to have their own procedure and I just want to get move the goods with the correct documentation.

My sincere apologies.

Nicola

### Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/+353 86 805 9380 T/+353 53 911 7929



HYPRED KIICO" (CONTRACTOR)

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From: Patti Cordo cordo@americancargoexpress.com

Sent: Wednesday 19 December 2018 14:58

**To:** Jerina Morris < <u>imorris@AmericanCargoExpress.com</u>>; Nicola Roche < <u>nicola.roche@kersia-group.com</u>>; Greg Low < <u>greglow@comcast.net</u>>

Cc: Sinead Walsh < sinead.walsh@kersia-group.com >; Debra Fierro < dfierro@contrapac.com >; Peter Fierro

contrapac.com; Mark Leonard <<pre><Mark.Leonard@hornerd.ie</pre>

Subject: RE: RETURN TO IRELAND -MEDENTECH

Nicola

What are you doing to rectify the discrepancy that the Customs Entry and the EPA letter? Did you speak to EPA to get this corrected?

This is a huge problem as the notice of redelivery issued by Customs is passed date and the EPA letter is not to Medentech

Nor does it reference an entry number. This must be resolved prior to export

Regards, Patti

Patti Cordo

Director of Import ACE USA & Canada American Cargo Express New Jersey Operations 2345 Vauxhall Rd Union, NJ 07083 Tel: 908-351-3400 x 3026

Tel. 900-351-3400 X 3026

Fax: 908-289-2490

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From: Tomczak, Kimberly < Tomczak. Kimberly @epa.gov>

Sent: Tuesday 18 December 2018 17:18
To: ESMERALDA.MARTINEZ@cbp.dhs.gov

Cc: Bauman, Michael <br/>
<br/>
bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Nicola Roche

<nicola.roche@kersia-group.com>

Subject: U16-10064192 and U16-10084042

Importance: High

Good afternoon,

The importer for Entry U16-10064192 and U16-10084042 has decided to export these shipments. We had communicated earlier this year about these shipments (see emails on July 25, 2018).

The attached letter allows the company to export the products. Can you provide information to the broker on what other documents are needed to export the two shipments? The broker has been copied on the email.

## Thank you for your assistance,

Kimberiy Tomezak, Life Scienosi US Environmental Protection Agency, Region 1 Posticides Section 61 Porsyth St. SW Adams, GA 30303

Phone: 104, 462,8987

tamati Tomczak.kimberly@epa.gov

From: Nicola Roche < nicola.roche@kersia-group.com >

Sent: Monday, December 17, 2018 11:34 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: FIFRA-04-2018-3257

Importance: High

Good afternoon Kimberly,
I hope my mail finds you well.

This query is with regard to FIFRA-04-2018-3257.

We have been trying to consolidate both consignments into a high cubed container to return the goods as promptly as possible to Medentech.

However, the export company used by our carriers have advised that we can only move the goods under CBP supervision. The attached CBP form is related to the first shipment.

I have forwarded your attached letter of release and advised supervision is not required.

The export company believes I need additional clearance from the EPA and at this point I really do not know what that is.

I sincerely apologise for contacting you, but if you can help at all I would be extremely grateful.

My very best regards Nicola

Nicola ROCHE

Customer Relations & Communications Manager

nicola.roche@kersia-group.com M/ +353 86 805 9380 T/ +353 53 911 7929



HYPRED Kilco' Colores antigerm medentech G3



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From: Mark Leonard < Mark. Leonard@hornerd.ie>

Sent: Monday 17 December 2018 15:42

To: Nicola Roche < nicola.roche@kersia-group.com >; Neil Horner < Neil.Horner@hornerd.ie >

Cc: Sinead Walsh < sinead.walsh@kersia-group.com > Subject: RE: RETURN TO IRELAND -MEDENTECH

Hi Nicola,

our agents have advised:

"this is rejected Merchandise to be returned under CBP supervision

Note you will need to contact Nicola Roche at Medentech see attached

Until Medentech have resolved the outstanding issues we cannot proceed with the Return

**Thanks** 

Kind Regards, Mark.



### HORNER AGENCIES LTD.,

Registered Office: Unit 6, 21 Beechwood Close, Boghall Road, Bray, Co. Wicklow, A98 AN81, IRELAND. Registered in Dublin, Ireland No. 431611.

Main Tel: 00-353-1-2137940 / Fax: 00-353-1-2022011.

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<ACE SLI -revised Aug2018.xls>

## Tomczak, Kimberly

From:

Crane, John P < john.p.crane@zoetis.com>

Sent:

Friday, December 28, 2018 12:04 PM

To:

Tomczak, Kimberly

Cc:

Bauman, Michael; Ho, Kanoelehua; Harmer, Jennifer

Subject:

RE: Case No. FIFRA-04-2018-3257

Hi Kim:

Yes, Medentech is taking responsibility for exporting the product back to their plant in Ireland. I have no problem with you keeping the revised letter addressed to us (Zoetis). It can come to me at the address below.

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Friday, December 28, 2018 11:02 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Importance: High

NOTICE: This message originates from an external source.

Hi John and Jennifer,

I have been notified that the export letter needs to state that Medentech is responsible for exporting the products not Zoetis. Is Medentech responsible for the export of these products?

When we send out the revised letter, should it still be addressed to you?

#### Thank you,

Kunberly Comezak, Lale Scientist US Environmental Profection Agency, Region 7 Pesticides Section Of Forsyth St. SW Atlanta, GA 3030.)

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P < john.p.crane@zoetis.com>
Sent: Tuesday, November 20, 2018 12:56 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kim:

Jennifer is off on vacation this week hence the email from me.

Medentech is now ready to ship these two shipments back to Ireland. The broker has asked the question whether an EPA official needs to be present when the container is loaded at Contrapac. The attached EPA letter states "The EPA Region 4 is hereby allowing Zoetis to export the products back to a Medentech facility in Ireland." There is no mention of this needing the oversight of an EPA official. Please can you confirm that no EPA official needs to be present when the container is loaded for export.

Thank you.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 13, 2018 7:15 AM

To: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Crane, John P < <u>john.p.crane@zoetis.com</u>> Cc: Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

You can send one letter that states both pieces of information.

Please let me know if you have any additional questions.

#### Regards,

Kunberly Tourczak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 51 Forsyth St. SVV Adama, GA 30303 Phone: 404,562,8987 Email: Tomczak,kimberly@cpa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 12, 2018 7:49 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

I received the letter last Thursday informing Zoetis that we can export the two shipments listed in the SSURO. Within the SSURO, there is a request for a letter confirming that the product has been exported to and received at Medentech in Ireland. Can you please confirm that a single letter confirming both export and receipt will suffice or if the request is for two separate letters, one confirming export and another confirming receipt?

Thanks in advance for your assistance with this!

Regards,

Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 06, 2018 7:04 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

We hope to get a letter out to you shortly in regards to the next step.

If you do not receive anything by close of business on Thursday, November 8, please let me know.

Regards,

Kimberly Long zak, Ufe Sciengs: US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW. Atlania, GA 30303 Phone: 104,562,8987

Final: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 05, 2018 4:11 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > **Cc:** Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

John Crane is out of the office this week and so I am following up on the below shipment. Can you please advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks in advance!

Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Wednesday, October 31, 2018 4:03 PM **To:** Crane, John P < <u>iohn.p.crane@zoetis.com</u>>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

I am in discussions with my Supervisor about the steps that will need to be taken to get these shipments exported.

## I will be in touch with you tomorrow or Friday.

#### Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesnedes Scenon 61 Forsyth St. SW Adama, GA (3030)

Phone: 101.362.8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Tuesday, October 30, 2018 6:47 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Good morning Kimberly:

Are you able to advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Tuesday, October 23, 2018 3:33 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

Thank you for your message. We look forward to hearing back from you.

#### Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, October 23, 2018 3:16 PM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

#### Good afternoon,

I have reached out to my Supervisor in regards to this request and will get back in touch with you as soon as I can.

The shipment should remain where it is currently located until you hear back from the EPA Region 4 office.

#### Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Scientific of Forsyth St. SAV Arbana, CAV 20203 Phone, 404,562,8987 Email: Tomezak,kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael <a href="mailto:sauman.michael@epa.gov">s. Ho, Kanoelehua < ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane

Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks!

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<<u>ho.kanoelehua@epa.gov</u>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

## Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

### Thank you,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forseth St. SAV Athana, GA 30302 Phone: 404,562,8987 Famal: Tomezak,kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

### Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

**Subject:** RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

## Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

## Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section of Forsyth St. SW Atlanta, GA 20503 Phone: 104,562,8987

Email: Tomczak.kimberly@cpa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly < Tomczak, Kimberly@epa.gov >; Bauman, Michael < bauman.michael@epa.gov >

**Cc:** Crane, John P < <u>john.p.crane@zoetis.com</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < iohn.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

### Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

#### Thank you,

Kumberly Tomezak, Life Scienust US Environmental Protection Agency, Region 1 Pesticides Section of Forsyth St. SW Atlanta, GA 30300 Phone: 404.562.8987 Frmail: Tomezak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael <bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow..

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM

To: Bauman, Michael < bauman.michael@epa.gov >
Cc: Crane, John P < john.p.crane@zoetis.com >
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman.

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com
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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

**Sent:** Thursday, August 30, 2018 9:09 AM **To:** Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

Regards,

Kumberly Foniczak, Life Scientist US Luvironmenon Protection Agency, Region J Pesticides Section of Forsyth St. SW Atlanta, GA 30303 Phone: 404,562,8987 Finall: Tomczak, kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>; Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

#### Regards,

Kunberly Tomezak, Life Scienusi I S Environmental Protection Agency, Region i Pesticides Section of Forsyth St. SM Atlanta, GA 40303 Phone: 104,562,8987 Fradii: Tomezak,kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

## Regards,

Kimberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Sections 64 Forsyth St. SW Adama, GA 30303 Phone: 104,562,8987

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

Final: Tomczak.kimberly@epa.gov

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

**Subject:** Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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# Tomczak, Kimberly

From:

Sean Dunne <Sean.Dunne@oiaglobal.com>

Sent:

Tuesday, March 05, 2019 3:46 PM

To: Subject: Tomczak, Kimberly; earlean.j.grayson@cbp.dhs.gov; danny.r.griffin@cbp.dhs.gov FW: 7512+4647+U16-10064192, U16-10084042 Export Under Customs Supervision

Attachments:

CONTAINERS IN-GATE.pdf; 7512.pdf; 4647 Letter from the EPA.pdf

## Officers CBP and EPA

Please be advised that the reused merchandise which arrived under entry numbers U16-10064192, U16-10084042 have been in-gated for export at the Georgia Ports

Authority, Garden City GA (L738) under 7512(63) number 497921480 04 March 2019. The 2 containers are booked to a vessel scheduled to depart 10 March 2019.

Please advise if any further action by CBP or EPA is required for this export to take place?

## Status Notification Response for INB0000061 / 497921480

A response message has been received from Customs. Shown below is a summary of relevant information received in the message

# Message for HLCUDUB180400955

Disposition Code 1J(In-bond movement authorized: Bill of lading open)

Disposition Date 01-Mar-19 14 26

OREGON INTERNATIONAL AIR

FREIGHT CO

## Sean Dunne, LCB

OlA GLOBAL | www.oiaglobal.com | Direct: +1 503 415 3334 | Office: +1 732 802 2222 |

| Mobile : +1 201 312 3243 | SKYPE: oia.sean.dunne |

Newark Branch: 2345 Vauxhall Road, Union, New Jersey 07083

# Tomczak, Kimberly

From:

Crane, John P < john.p.crane@zoetis.com>

Sent:

Thursday, May 09, 2019 8:22 AM

To:

Tomczak, Kimberly

Cc:

Bauman, Michael; Ho, Kanoelehua; Harmer, Jennifer

Subject:

RE: Case No. FIFRA-04-2018-3257

Thank you Kim.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Sent: Thursday, May 9, 2019 7:10 AM

To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning,

You should received the termination letter later this week or first thing next week.

I apologize for the delay in getting you the letter.

Regards,

Kumberk Tomezak, Jale Sciences

US Environmental Presection Agency, Region 3

Chemical Sales, Scenere

61 Lorsoth St. SW Minns (A) 305-07

Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P < john.p.crane@zoetis.com>

Sent: Thursday, May 09, 2019 7:05 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim:

We sent the attached letter to Kimberly Bingham on April 3, 2019 advising that Medentech had received the two shipments of Inovotabs at their facility in Ireland and requesting that EPA send us notification that the SSURO (attached) had been vacated.

Medentech is now re-labeling these packs with an opaque oversticker and intends to reexport the product back to the US for distribution and sale as soon as possible.

Under section 21, the SSURO states "Zoetis shall not commence any sale, use, removal or distribution of the cases of Inovotabs unless: (1) Zoetis is in compliance with FIFRA and has taken all actions required in Section II of this SSURO; and (2) the EPA has vacated this SSURO." It also mentions the submission of certification of compliance with FIFRA and photographs of relabeled packs.

Please can you advise when we will be receiving the vacate letter. Or is it the case that you need submission of certification of compliance with FIFRA and photographs of relabeled packs from Medentech before EPA sends us the vacate letter? The SSURO might suggest that the latter only applies to the situation where these packs were going to be relabeled at Contrapac in the US (see Section 20 of the SSURO). Please can you kindly advise.

Thank you in advance.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Friday, December 28, 2018 12:04 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim:

Yes, Medentech is taking responsibility for exporting the product back to their plant in Ireland. I have no problem with you keeping the revised letter addressed to us (Zoetis). It can come to me at the address below.

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Friday, December 28, 2018 11:02 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Importance: High

NOTICE: This message originates from an external source.

Hi John and Jennifer,

I have been notified that the export letter needs to state that Medentech is responsible for exporting the products not Zoetis. Is Medentech responsible for the export of these products?

# When we send out the revised letter, should it still be addressed to you?

# Thank you,

Kumberly Tomovak, Life Scienisi US Linymoniae utal Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adama, GA 30503

Phone: 104, 362,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P < john.p.crane@zoetis.com > Sent: Tuesday, November 20, 2018 12:56 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Bauman, Michael <br/>
<a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kim:

Jennifer is off on vacation this week hence the email from me.

Medentech is now ready to ship these two shipments back to Ireland. The broker has asked the question whether an EPA official needs to be present when the container is loaded at Contrapac. The attached EPA letter states "The EPA Region 4 is hereby allowing Zoetis to export the products back to a Medentech facility in Ireland." There is no mention of this needing the oversight of an EPA official. Please can you confirm that no EPA official needs to be present when the container is loaded for export.

Thank you.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 13, 2018 7:15 AM

**To:** Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>; Crane, John P < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>; Crane, John P < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>; Ho, Kanoelehua < <a href="mailto:ho.kanoelehua@epa.gov">ho.kanoelehua@epa.gov</a>>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

You can send one letter that states both pieces of information.

Please let me know if you have any additional questions.

## Regards,

Kimberly Lomezak, Life Scienust US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adamia, CAN 30303 Phone: 404,562,8987 Limil: Tomezak,kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 12, 2018 7:49 AM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

I received the letter last Thursday informing Zoetis that we can export the two shipments listed in the SSURO. Within the SSURO, there is a request for a letter confirming that the product has been exported to and received at Medentech in Ireland. Can you please confirm that a single letter confirming both export and receipt will suffice or if the request is for two separate letters, one confirming export and another confirming receipt?

Thanks in advance for your assistance with this!

Regards,

Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, November 06, 2018 7:04 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Crane, John P < john.p.crane@zoetis.com >

**Cc:** Bauman, Michael < <u>bauman.michael@epa.gov</u>>; Ho, Kanoelehua < <u>ho.kanoelehua@epa.gov</u>> **Subject:** RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

We hope to get a letter out to you shortly in regards to the next step.

If you do not receive anything by close of business on Thursday, November 8, please let me know.

Regards,

Kimberly Toroczak, Life Sciencist US Environmental Protection Agency, Region v Pesticines Section Of Forsyth St. SW Atlanta, GAY 2013021 Phone: 104,562,8987 Email: Tomczak,kimberly@epa.gov

From: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Sent: Monday, November 05, 2018 4:11 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov >; Crane, John P < john.p.crane@zoetis.com > Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

John Crane is out of the office this week and so I am following up on the below shipment. Can you please advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks in advance! Jennifer

From: Tomczak, Kimberly [mailto:Tomczak,Kimberly@epa.gov]

**Sent:** Wednesday, October 31, 2018 4:03 PM **To:** Crane, John P < <u>john.p.crane@zoetis.com</u>>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

I am in discussions with my Supervisor about the steps that will need to be taken to get these shipments exported.

# I will be in touch with you tomorrow or Friday.

## Regards,

Kumberly Lomezak, Lafe Scienisi US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adams, GA 30303 Phone, 104,562,8987

tanat: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Tuesday, October 30, 2018 6:47 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Good morning Kimberly:

Are you able to advise on next steps to export this consignment at Contrapac back to Medentech, Ireland?

Thanks, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007 Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Crane, John P

Sent: Tuesday, October 23, 2018 3:33 PM

To: Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua < ho.kanoelehua@epa.gov >; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

Thank you for your message. We look forward to hearing back from you.

# Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Tuesday, October 23, 2018 3:16 PM
To: Crane, John P < john.p.crane@zoetis.com >

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

# Good afternoon,

I have reached out to my Supervisor in regards to this request and will get back in touch with you as soon as I can.

The shipment should remain where it is currently located until you hear back from the EPA Region 4 office.

# Thank you,

Kimberly Tomezak, Life Scienist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adams, GA 30305 Phone: 404,562,8987 Email: Tomezak,kimberly@epa.gov

Timan. Tomezak.kumeriyesepa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Monday, October 22, 2018 11:30 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua < ho.kanoelehua@epa.gov>; Harmer, Jennifer

<jennifer.harmer@zoetis.com>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Kimberly:

My colleague Jennifer Harmer is travelling this week hence this email from me.

The relabeling operation was commenced last week at Contrapac but it was found that the wording from the original label was not completely obscured by the new label, so the operation was immediately halted.

Medentec has now decided to export the two shipments back to their facility in Ireland and relabel or repackage there. Please can you advise as to what is needed from EPA to allow this export (SSURO, II. ORDER, 20. (a)). I am not sure if we need another letter releasing these two shipments from the SSURO.

Thank you in advance.

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Harmer, Jennifer

Sent: Thursday, October 18, 2018 11:35 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kim,

Attached are the labels that will be used for relabeling the two shipments.

Please do not hesitate to contact me with additional questions or concerns.

Thanks!

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 innifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, October 18, 2018 9:40 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

< ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

## Good morning,

Thank you for the update. Can you send me a copy of the label that you plan to use for relabeling the products?

# Thank you,

Knitherly Fornezat, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Atlanta, GA 30003 Phone: 404,562,8987

Limail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, October 18, 2018 9:15 AM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

**Subject:** RE: Case No. FIFRA-04-2018-3257

Hello Kimberly,

In response to your questions below, please note that the re-labeling of the two shipments outlined in the SSURO is in progress. We anticipate that the relabeling will be completed next week. We will be in touch once the relabeling is complete.

Please do not hesitate to contact me with any additional questions.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, October 17, 2018 5:43 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com>

Cc: Crane, John P < john.p.crane@zoetis.com>; Bauman, Michael < bauman.michael@epa.gov>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Good afternoon,

What is the status of these two shipments that are outlined in the SSURO? Have they been relabeled?

# Regards,

Kumberly Tomezak, Life Scientisi US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Atlanta, GA 3030°; Phone: 404.562.8987

Lauril: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Thursday, September 27, 2018 5:11 PM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Bauman, Michael <bay>
<br/>bauman.michael@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I am writing to follow-up on the amendment to the SSURO. Do you happen to have any information on when we can expect to receive the amendment?

Thanks in advance!

Jennifer

From: Harmer, Jennifer

Sent: Wednesday, September 19, 2018 5:33 PM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>; Bauman, Michael < bauman.michael@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

# Hi Kimberly,

There is an error in the number below. The correct establishment number is 52270-GA-03 and the address is 5400 Bucknell Drive, Atlanta, GA 30336.

Apologies for the confusion and thanks again for your assistance.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, September 19, 2018 4:37 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Below you state that you would like to relabel the product at EPA Est. No. 52770-GA-03. Is that the correct number?

## Thank you,

Kumberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section GL Corsyth St. SW Adams., CA 50307 Phone: 104,562,8987

Email: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 1:44 PM

To: Bauman, Michael <bauman.michael@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

Thank you for the information. I will discuss with Officer Tomczak when she returns to the office tomorrow.

Thanks! Jennifer

From: Bauman, Michael [mailto:bauman.michael@epa.gov]

Sent: Monday, September 17, 2018 11:54 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com>; Tomczak, Kimberly < Tomczak.Kimberly@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Good morning Ms. Harmer,

At this time, the product's location and any manipulation of the product must remain in compliance with the SSURO that has been issued. Prior to the product being moved, the Stop, Sale, Use or Removal Order (SSURO) would require an amendment that must be signed and issued in a similar fashion with which the original SSURO was issued and under the same docket number.

If you still wish request that the SSURO be amended to accommodate the change described below, please discuss the matter further with Ms. Tomczak when she returns to the office tomorrow..

Regards, Michael

Michael L. Bauman, MS | Life Scientist, Pesticides Section | Chemical Safety and Enforcement Branch Air, Pesticides and Toxics Management Division | U.S. Environmental Protection Agency Region 4 61 Forsyth Street, SW Atlanta, GA 30303 | Tel: 404-562-8962 | Email: <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>

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From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, September 17, 2018 11:36 AM

To: Bauman, Michael < bauman.michael@epa.gov >
Cc: Crane, John P < john.p.crane@zoetis.com >
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Bauman,

I just received Officer Tomczak's out of office and so am hoping you can address a question that we have regarding Case No. FIFRA-04-2018-3257.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility (EPA Establishment Number 52770-GA-03) is acceptable and complies with the requirements of the SSURO?

Thanks in advance for your assistance and I look forward to hearing from you.

Regards, Jennifer

Jennifer G. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Harmer, Jennifer

Sent: Monday, September 17, 2018 11:27 AM

To: 'Tomczak, Kimberly' < Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: FW: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Happy Monday! I hope you had an enjoyable weekend.

Page 6 of the attached SSURO states that relabeling must occur at Contrapac, Inc. located at 675 Southwest Parkway, Atlanta, GA 30036 (EPA Establishment Number 52270-GA-001). Due to capacity issues, Contrapac and Zoetis are proposing to have the relabeling take place at Contrapac's facility that is around the block from the facility cited in the SSURO. Specifically, the relabeling will take place at Contrapac, Inc. located at 5400 Bucknell Drive, Atlanta, GA 30036 (EPA Establishment Number 52770-GA-03). This facility is registered with the EPA and performs relabeling operations. Zoetis will include the address and establishment number of the Contrapac location on Bucknell Drive on the label.

Can you please confirm that relabeling at this facility is acceptable and complies with the requirements of the SSURO?

Thanks! Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 9:09 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < iennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi John,

Other shipments of the product can be imported. The label should be in compliance of FIFRA.

## Regards,

Kimberly Fourczak, Life Scientist US Povironniental Protection Agency, Region 1 Pesticides Section 64 Fotsyth St. SW Arkana, GA 30203 Phone: 404,502,8987

Email: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Thursday, August 30, 2018 9:02 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>; Bauman, Michael < <a href="mailto:bauman.michael@epa.gov">bauman.michael@epa.gov</a>; Ho, Kanoelehua

<ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

Thanks Kimberly. In answer to your question, I have just had it confirmed that no we do not.

Best regards, John

John P. Crane

Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 30, 2018 8:04 AM
To: Crane, John P < john.p.crane@zoetis.com>

Cc: Harmer, Jennifer < jennifer.harmer@zoetis.com >; Bauman, Michael < bauman.michael@epa.gov >; Ho, Kanoelehua

< ho.kanoelehua@epa.gov>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi John,

The SSURO only applies to the two shipments in the SSURO.

Do you have another shipment that arrived in the US that contains the same misbranded product?

#### Regards,

Kimberly Tomezak, Lafe Scienus; US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Adama, CA 30303 Phone: 404,562,8987

1 110110. 1747.192.0 707

tomai: Tomczak.kimberly@epa.gov

From: Crane, John P [mailto:john.p.crane@zoetis.com]

Sent: Wednesday, August 29, 2018 1:30 PM

**To:** Tomczak, Kimberly < Tomczak.Kimberly@epa.gov > **Cc:** Harmer, Jennifer < jennifer.harmer@zoetis.com >

Subject: RE: Case No. FIFRA-04-2018-3257

Dear Kimberly:

Jennifer is on vacation this week so I contacting you. I have an update and a question.

The update is that we have corrected the labeling and will be printing those shortly for the relabeling operation at Contrapac. Once completed we will be sending you the pictures plus the certification letter of compliance.

Regarding the SSURO (attached), please can you confirm that this only applies to the two on-hold consignments specified in the SSURO. I ask because we have new stock on order that will be labeled with fully compliant labeling and which might be ready for shipment from Medentech, Ireland to the US even before we receive the vacate letter from EPA for the two on-hold consignments. We are looking for confirmation that we are ok to do that.

Many thanks.

Best regards, John

John P. Grane Director, US Regulatory Affairs Veterinary Medicines Research and Development 333 Portage Street, Kalamazoo, Michigan 49007

Office: 269.359.9098 | Cell: 269.760.1241 | john.p.crane@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Thursday, August 23, 2018 4:24 PM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com > Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A photo of each stack will suffice.

I hope that helps. If you would like to discuss further, please let me know.

Regards,

Kumberly Tomezak, Life Scientist US Environmental Protection Agency, Region 4 Pesticides Section 61 Forsyth St. SW Adama, GA 30303 Phone: 404,562,8987

Linail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Wednesday, August 22, 2018 1:09 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov >

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

Thanks for your message. To make sure I understand the requirements, can you please clarify if a photo of each stack, with a few individual units for detail would be sufficient or is the requirement to send a photo of each individual unit?

Thanks in advance for your assistance!

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Wednesday, August 22, 2018 9:54 AM

To: Harmer, Jennifer < <a href="mailto:jennifer.harmer@zoetis.com">jennifer.harmer@zoetis.com</a>>

Cc: Crane, John P < john.p.crane@zoetis.com > Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

A variety of different pictures will be needed. Please provide legible pictures of the label on the product (labels from each entry) and a picture of the container/tub itself. In addition, provide pictures of all the tubs, if they are stacked together.

I hope that helps. If you would like to discuss further, please let me know.

# Regards,

Kunberly Tomezak, Life Scientist US Environmental Protection Agency, Region 1 Pesticides Section 61 Forsyth St. SW Adapta, GA 30303 Phone: 404,562,8987

I mail: Tomczak.kimberly@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Tuesday, August 21, 2018 2:27 PM

To: Tomczak, Kimberly < Tomczak. Kimberly@epa.gov>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hi Kimberly,

I hope your Tuesday is going well!

Following our call yesterday, we have an additional question regarding the SSURO. Specifically, point 20(b)(ii) requires Zoetis to submit pictures to the EPA of the re-labeled cases. Can you help us to understand the expectations for the pictures? Is a picture of one tub and one outer carton sufficient or should we submit pictures of a certain percentage of the cases? If more than one picture is required, can you please specify the number or percentage of cases for which we should submit pictures?

Thanks in advance for your assistance. We really appreciate your support.

Regards, Jennifer

From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 3:12 PM

To: Harmer, Jennifer < <u>jennifer.harmer@zoetis.com</u>>
Cc: Crane, John P < <u>john.p.crane@zoetis.com</u>>
Subject: RE: Case No. FJFRA-04-2018-3257

NOTICE: This message originates from an external source.

Hi Jennifer,

It was nice talking with you earlier.

Glad I could be of assistance. I will wait to hear back from you when the product has been relabeled.

# Regards,

Kunberly Tomezak, Life Scienusi 1 S Environmental Protection Agency, Region 1 Pesticides Section to Forsyth St. SW Adama, GA 30303 Phone: 404,562,8987

Finail: Tomczak.kimberly@cpa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Monday, August 20, 2018 2:44 PM

**To:** Tomczak, Kimberly < <u>Tomczak.Kimberly@epa.gov</u>>

Cc: Crane, John P < <u>iohn.p.crane@zoetis.com</u>>
Subject: RE: Case No. FIFRA-04-2018-3257

Hello Officer Tomczak,

Thanks again for meeting with us to discuss Case No. FIFRA-04-2018-3257. As discussed, we are in receipt of the SSURO and are working to resolve the labeling discrepancies that you identified. Additionally, we have done a line by line review of the artwork and have made some additional minor revisions in order to comply with the master label. The additional revisions include typos, formatting changes, and an update to the Environmental Hazards section to comply with the language on the master label for end-use products packaged in containers with sizes of less than 50 pounds. The marked up artwork was sent to Medentech on Friday, August 17<sup>th</sup> with a request to expedite these label revisions. Once the artwork has been revised it will be sent to Contrapac, Inc. so that they may overlabel the two shipments of product that are subject to the SSURO. Product that is relabeled by Contrapac will include Contrapac's establishment number (EPA Est. 52270-GA-001) in line with Chapter 14 of the Label Review Manual and 40 CFR 156.10(f) which requires labels to bear the establishment number of the final establishment at which the product was produced. Within 48 hours after completion of relabeling, we plan to submit to the EPA pictures of the re-labeled cases along with a certification that the re-labeling has been completed.

We understand that following receipt of the photos and certification, EPA will verify compliance with the SSURO and then issue a vacate letter at which time we may distribute the product.

Thanks again for meeting with us this afternoon. We found the discussion to be really helpful. Please reach out to me with any questions or concerns.

Regards,

Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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From: Tomczak, Kimberly [mailto:Tomczak.Kimberly@epa.gov]

Sent: Monday, August 20, 2018 10:16 AM

To: Harmer, Jennifer < jennifer.harmer@zoetis.com >

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<jmessina@exponent.com>

Subject: RE: Case No. FIFRA-04-2018-3257

NOTICE: This message originates from an external source

Hi Jennifer,

Yes, I am available today to discuss Case No. FIFRA-04-2018-3257.

I am available anytime today until 5PM. Let me know what time works best for you.

# Regards,

Kunberty Tomezak, Life Scientist 1-5 Lavironmental Protection Agency, Region 4 Pesticides Section 64 Forseth St. SW. Adamia, GA 30373 Phone, 404,562,8987 Email: Tomezak,kimberty@epa.gov

From: Harmer, Jennifer [mailto:jennifer.harmer@zoetis.com]

Sent: Friday, August 17, 2018 11:17 AM

To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>

Cc: Crane, John P < john.p.crane@zoetis.com >; Sebley, Christopher H < christopher.sebley@zoetis.com >; James Messina

<imessina@exponent.com>

Subject: Case No. FIFRA-04-2018-3257

Dear Officer Tomczak,

I would first like to introduce myself. My name is Jennifer Harmer and I am in the US Regulatory Affairs group at Zoetis. I am writing in regards to Case No. FIFRA-04-2018-3257 for Inovotabs (EPA Registration Number 71847-3-1007). We are currently working to address the comments in the letter. Do you happen to have any availability on Monday, August 20<sup>th</sup> for a phone call? We would like to provide you with the current status of the request and the actions we intend to take comply with the SSURO. Attendees on the call from my side would include myself, John Crane (Head of US Regulatory Affairs, Zoetis), and Jim Messina (Consultant, Exponent).

Thanks in advance and I look forward to speaking with you.

Regards, Jennifer

Jennifer C. Harmer

Associate Director, US Regulatory Affairs
Veterinary Medicines Research and Development
333 Portage Street, Kalamazoo, Michigan 49007
Office: 269.359.4857 | jennifer.harmer@zoetis.com

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